MEDICARE CHRONIC CARE IMPROVEMENT PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

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MEDICARE CHRONIC CARE IMPROVEMENT PROGRAM

TUESDAY, MAY 11, 2004

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:14 p.m., in room 1100, Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
May 04, 2004
HL–8

CONTACT: 202–225–3943

Johnson Announces Hearing on Medicare Chronic Care Improvement Program

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on the Chronic Care Improvement Program authorized by the Medicare Modernization Act. **The hearing will take place on Tuesday, May 11, 2004, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 2:00 p.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108–173) that was signed on December 8, 2003, Congress provided for a Chronic Care Improvement Program (CCIP) within fee-for-service Medicare. On April 20, 2004, the Centers for Medicare and Medicaid Services (CMS) released a Request for Proposals (RFP) for chronic care improvement programs focused on congestive heart failure, diabetes, and chronic obstructive pulmonary disease. CMS will select programs to operate in 10 regions of the country to evaluate different approaches to the management of chronic conditions. The initial phase of the CCIP will be based on improved quality in health outcomes, beneficiary satisfaction, and financial savings to the Medicare program.

Medicare beneficiaries with five or more chronic conditions represent 20 percent of the Medicare population but account for 66 percent of program spending. The CCIP represents a new way of approaching the care of beneficiaries within the fee-for-service program by shifting from a focus on acute episodes to the management of on-going chronic conditions.

In announcing the hearing, Chairman Johnson stated, "The chronic care improvement program is a major step forward for the Medicare program and the quality of health care it provides. It represents a fundamental shift in how we think about caring for our seniors and people with disabilities. This is a key element of how the Medicare Modernization Act truly *modernizes* the Medicare program by improving discussion and coordination between Medicare beneficiaries and their physicians."

FOCUS OF THE HEARING:

CMS released the RFP for the CCIP on April 20, 2004. Proposals are due back to the agency in early August. Panel members at the hearing will include representatives from prospective bidders, physician groups, and beneficiary organizations. The hearing continues the series of hearings held by the Subcommittee on the implementation of the Medicare Modernization Act.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person or organization wishing to submit written comments for the record must send it electronically to hearingclerks.waysandmeans@mail.house.gov, along with a fax copy to (202) 225-2610, by close of business Tuesday, May 25, 2004. In the immediate future, the Committee website will allow for electronic submissions to be included in the printed record. Before submitting your comments, check to see if this function is available. **Finally,** due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-packaged deliveries to all House Office Buildings.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. Due to the change in House mail policy, all statements and any accompanying exhibits for printing must be submitted electronically to *hearingclerks.waysandmeans@mail.house.gov*, along with a fax copy to (202) 225–2610, in WordPerfect or MS Word format and MUST NOT exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Any statements must include a list of all clients, persons, or organizations on whose behalf the witness appears. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON. Today, I am pleased to chair this hearing on the Chronic Care Improvement Program (CCIP) that was passed as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108–173). The program is a major step forward for the Medicare Program and the quality of health care that it provides. It represents a fundamental shift in how we think about caring for our seniors and people with disabilities. The CCIP is a key element in how the MMA truly modernizes the Medicare Program by improving discussion and coordination between Medicare beneficiaries and their physicians.

Medicare beneficiaries with five or more chronic conditions represent 20 percent of the Medicare population that account for 66 percent of the program spending. The CCIP represents a new way of approaching the care for beneficiaries within the fee-for-service program by shifting from a focus on acute episodes to the management of ongoing chronic conditions.

This new way of thinking will become even more essential as we approach the retirement of the baby boom generation. The 40 million beneficiaries currently in Medicare will double to more than 80

million over the next 30 years. More and more of those beneficiaries will be living with chronic conditions. The steps we are taking today to rethink how Medicare provides health care will be essential as the number of beneficiaries increases in future years. The Centers for Medicare and Medicaid Services (CMS) currently has several demonstration projects in place to test various types of disease management programs, but none matches the scale and scope of the CCIP included in last year's Medicare law.

I am extremely happy that this fundamental change in the program is rapidly being implemented. To a large degree, that is as a result of the firm resolve and strong support for this program from Members of Congress, Secretary Thompson, and Administrator McClellan as well as his staff.

The CMS released this Request For Proposal (RFP) on April 20 and will carry out Phase I of the CCIP in 10 regions of the country over the next 3 years. The first phase will focus on beneficiaries with congestive heart failure, diabetes, and chronic obstructive pulmonary disease. The initial phase of the CCIP will be based on improved quality and health outcomes, beneficiary satisfaction, and financial savings to the Medicare program, and successful programs will be expanded to more beneficiaries in the fee-for-service program.

I might point out that this is the first time we have been able to build into Medicare a capacity on the part of the Secretary to pilot things that will make a positive health improvement in our seniors and then to roll them out automatically under his authority. This will accelerate the pace at which quality improvements in Medicare actually become available by not requiring that Congress have another vote, another bill, another go, before positive changes can be implemented in Medicare.

I welcome today Dr. Mark McClellan in his first appearance before Congress as CMS Administrator. It is really a pleasure to welcome you, Mark. You have broad experience both in government and as a physician; and I welcome you before our panel to discuss CMS plans for implementing this terribly important program that I know you are not only well familiar with, but a strong advocate of.

I also look forward to the testimony of our second panel, Christobel Selecky, President-Elect of the Disease Management Association of America, who will provide us with some insights into the ways in which various organizations are working together to respond to the RFPs for this program. Dr. Janet Wright, speaking on behalf of the American College of Cardiologists, will provide a practicing physician's viewpoint on the importance of the CCIP to the Medicare population.

Dr. Vince Bufalino from the American Heart Association (AHA) will discuss the impact that CCIPs can have on the lives of beneficiaries; and Dr. Robert Berenson of the Urban Institute had planned to provide us with a researcher's perspective on the program. Unfortunately, they had an evacuation of the airport from which he was to leave, and it is extremely unlikely he will be able to join us. His testimony is very important both to the consideration of this RFP in the long term, to our consideration of how we reform our payment system for physicians. So, we will consider his

testimony as part of the base from which we will question panelists, and we will share that testimony with him at a time when he can be present.

[The prepared statement of Dr. Berenson follows:]

Statement of Robert A. Berenson, Urban Institute

Madame Chairman, Mr. Stark, and members of the subcommittee: Thank you for inviting me to this important session dedicated to reviewing the challenge of better serving the growing number of Medicare beneficiaries with multiple and complex chronic conditions.

Americans are living longer than ever, because of new medical treatments and technologies, better prevention, and healthier lifestyles. At the same time, people are living longer with chronic conditions, such as heart disease, diabetes, neuro-degenerative diseases, and even cancer. Diseases that used to be fatal early on in their course can now be managed effectively for years. And as we live longer, more of us are contending with multiple and complex chronic conditions that require a high degree of medical management and monitoring and a new commitment to encouraging and supporting patient self-management.

Policymakers are just beginning to realize the implications for Medicare of beneficiaries living longer with chronic illness, particularly multiple chronic diseases.[1] About 20 percent of beneficiaries have five or more chronic conditions, account for over two-thirds of Medicare spending, see about 14 different physicians in a year, and have almost 40 office visits.[2] The chances of an otherwise unnecessary hospitalization—for conditions that can and should be managed effectively on an outpatient basis—increase from about 1 percent for a beneficiary with just one condition to about 13 percent for a beneficiary with five conditions and about 27 percent for a person with eight chronic conditions.[3] It would seem then that beneficiaries with multiple chronic conditions have unattended complications despite their high health care use. It also would appear that the number of chronic conditions has more influence than age on health care spending in the Medicare population.[4]

Section 721 of the Medicare Modernization Act (MMA) provides for a new Chronic Care Improvement (CCI) program within the traditional Medicare program; the law also requires a new emphasis on chronic illness management within the restructured Medicare Advantage program. The CCI program is essentially a vendor-operated disease management program targeting beneficiaries with chronic obstructive pulmonary disease, congestive heart failure, diabetes mellitus, and other diseases that the Secretary may specify. The Centers for Medicare and Medicaid Services (CMS) recently published a Request for Proposals that makes clear that entities other than a disease management organizations are encouraged to apply, although the emphasis will be on organizations with large scale and scope, because of the risk requirement, generally far beyond that of even large group practices. The CCI will be tested for three years after which the Secretary will evaluate the program for financial outcomes (program savings), clinical quality (hospital readmission rates and adherence to clinical guidelines), and beneficiary satisfaction.

In general, a CCI vendor must guide beneficiaries in managing their health. Every enrolled beneficiary will have a care plan that is to include disease self-management education and collaboration with physicians and other providers to enhance communication of relevant clinical information. Care plans can also include use of monitoring devices to facilitate transmission of clinical indicators. CCI vendors must also have tracking systems to follow beneficiaries across settings and record and monitor outcomes in each setting.

In recent years, there has been growing dissonance between the evolving use of disease management by private health plans, convinced of its utility in improving patient care, and the continuing dearth of peer-reviewed evidence of its cost-effec-

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[1] Among a number of recent policy documents that examine the issue of chronic conditions and Medicare is Eichner, June and Blumenthal, David, eds. *Medicare in the 21st Century: Building a Better Chronic Care System.* National Academy of Social Insurance. Washington, DC. January 2003.

[2] Partnership for Solutions, *Medicare: Cost and Prevalence of Chronic Conditions.* Johns Hopkins University, Baltimore, MD. July 2002.

[3] Wolff J. et al. *Archives of Internal Medicine*, November 11, 2002.

[4] Berenson R, Horvath J, *Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reforms*. Prepared for the Center for Medicare Advocacy, March 2002. Accessed February 2004, www.partnershipforsolutions.org/DMS/files/MedBeneficiaries2-03.pdf. It is also true that the presence of chronic conditions is associated with age; however, costs and use are similar for beneficiaries with multiple chronic conditions regardless of age.

tiveness. One desirable aspect of the CCI program is that the technique will be tested in formal trials that should help provide data to better assess the cost-effectiveness of disease management for the Medicare population in the context of the traditional Medicare program.

I would direct the subcommittee's attention to a potential problem in the study design mandated in the MMA. The requirement that individual patients are to be randomized to intervention and control will make it very difficult for practice-based organizations to compete for an award because such an organization would normally provide the intervention to all of its patients that would benefit from the care coordination approach. For these applicants a trial that permits matching rather than randomization would be more appropriate. I would urge the Congress to give the CMS the flexibility to a study design that accommodates the circumstances of different applicants.

Although the CCI program may be a good start, in my opinion it is insufficient for truly addressing chronic care needs in Medicare because it lacks a focused physician component. The Administration emphasizes that the new program creates a "business platform" that will permit innovation, but the CCI program ignore the reality that beneficiaries look to their personal physicians for responsibility for their health care—and not business platforms—whether health plans, disease management companies, or other third party-vendors.

Policymakers need to tackle the difficult challenge of engaging those responsible for health care quality and use, namely the doctors and other health care professionals. Further, in order to be successful, disease management and related case management should work better with the active involvement of the patient's physician.[5] Again and again studies have shown that care coordination only works with real physician involvement. Unfortunately, the CCI initiative is quite removed from the physician, although the legislation correctly calls for an individual's care plan to include physician education and collaboration.

Consistent with the overall philosophy of the MMA, this approach to addressing the growing need for improved care for those with chronic health conditions is a corporate one, focused on providing contracts to third-party vendors, rather than directly enabling professionals to better serve their patients. The traditional Medicare program has an unrealized opportunity to lead the restructuring of how physicians organize and deliver health services, as called for by the Institute of Medicine in its seminal "Crossing the Quality Chasm" report.[6] Instead, the MMA would have Medicare merely follow private sector approaches have been tested in younger and somewhat healthier populations and that may not be as well suited to the Medicare beneficiaries.

Disease management can likely bring important benefits, such as improved functioning and decreased hospitalizations, to relatively healthy individuals, with a well-defined chronic condition. It is also proper that CCI programs are required to identify and address enrollee co-morbidities. However, these programs have not generally been designed to address successfully the needs of medically complex patients, whose needs go well beyond learning disease self—management techniques and who have multiple professionals affecting the care and treatments of their different conditions. Nor are they designed to meet the needs of individuals with dementia, and, therefore cannot benefit form disease management's heavy emphasis on patient self-education.

It will be challenging for disease management companies and other vendors who may be awarded contracts under the initiative to develop the necessary links with physicians, especially because the law provides no new reason for physicians to engage with them. Creating effective relationships with treating physicians is further complicated by the probability that these management companies will be operating across great distances from a central location with no particular connection to the communities in which they will operate.

Medicare disease management would benefit a certain segment of beneficiaries, and this approach could certainly be part of a comprehensive strategy to improve the care provided to Medicare beneficiaries with multiple chronic conditions. But it is not a sufficient response.

These private-sector approaches have arisen partly because many physicians have been impervious to the altered needs of a patient population with far more well-established, chronic conditions and far fewer acute medical events than their training

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[5] Chen, A, Brown, R; et al. *Best Practices in Coordinated Care*. Prepared for the Health Care Financing Administration. Mathematica Policy Research, Princeton, NJ. March 2000. Accessed February 2004 at www.mathematica-mpr.com/pdfs/bestsum.pdf.

[6] Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academy of Sciences. Washington, DC. March 2001.

has prepared them for. In addition, the financial underpinnings of a typical medical practice do not support physicians who actually do recognize the need to be more fully engaged in the components of chronic care coordination. These include: teaching patient self-management; communicating more often with patients outside of face-to-face office visits; managing polypharmacy; coordinating care among many other professionals and providers to avoid redundancy and errors; developing and maintaining more appropriate medical information summaries, preferably inside an electronic health record; and more forthrightly helping prepare patients and their families for death and dying. Simply stated, the Medicare payment system does not pay for these activities, so physicians either do not deliver these services directly or go unpaid when trying to do so.

Bounced around the system, too many Medicare beneficiaries do not even recognize a particular physician who is responsible for coordinating their care. Where no physician is in charge, disease management certainly serves a useful stopgap role. Nevertheless, the program goal should be to promote a patient relationship with a primary care physician or a specialist willing to take overall responsibility for care coordination and the other functions that I identified earlier. Although disease management can assist a patient's primary physician in caring for patients with multiple chronic conditions, its role should be viewed clearly as supplementary to the personal physician's responsibility. Disease management currently appears to serve a useful purpose because of a quality chasm in how health care is delivered. The policy objective should be to address the causes of the chasm and not merely provide a partial stopgap.

As stated earlier, among other areas that need attention is the overlooked issue of physician payment policy. Simply put, the incentives inherent in most fee-for-service payment systems, including Medicare's and those of most private payers, penalize primary care physicians who would alter their professional interactions with patients to respond to the challenge posed by the reality of patients with multiple complex chronic conditions.

Yet, the MMA mostly ignores alternative payment approaches affecting physician behavior. These payment approaches should go hand in hand with the new chronic care program to ensure the kind of change needed to improve care for Medicare beneficiaries. I would note that Sec 646 of the MMA, the Medicare Health Care Quality Demonstration Program, provides a possible platform for examining new payment approaches. This demonstration should be given high priority and should explicitly address chronic care improvement incentives for physicians and medical groups.

Imagine if in the early 1980s, Congress, confronted with soaring Medicare Part A hospital costs produced partly as a result of an inherently inflationary, cost-plus payment system, had decided not to implement the Prospective Payment System. Imagine, instead, that Congress had chosen to fund third-party vendor, utilization review organizations to try to reduce lengths of stay for Medicare patients. That approach might have had some marginal beneficial effects on cost reduction—and plenty of unpleasant confrontations with physicians and hospital staff. Overall, trying to improve hospital efficiency while ignoring the incentives inherent in the basic payment system would have been foolhardy. Congress showed good sense by going to the root of the problem.

I would argue that we now face a similar challenge to get the physician payment systems right, and to do so would mean entering mostly unchartered territory. But is it logical to think you can improve the medical care provided to Medicare beneficiaries with chronic conditions while ignoring physicians?

One of the problems, of course, is that the medical profession itself has been slow to recognize that the nature of the practice of medicine is changing and it has not been very assertive in proposing new billing codes and payment approaches that would support altered physician activities. Indeed, as I noted above, I am not sure that most physicians even recognize the care gaps that result from maintaining a traditional orientation to responding expertly to acute medical events, while ignoring the less dramatic, but significant, needs of those with progressive chronic conditions.

Recently, the specialty associations representing the primary care physicians who serve Medicare beneficiaries, including the American Academy of Family Physicians, the American College of Physicians, and the American Geriatric Society, have begun to address this particular quality gap and have supported specific legislation that I believe goes in the right direction. I urge the Committee to work with these and other interested parties to explore new payment approaches that should be intrinsic to any serious effort to refocus Medicare on the unique burden of chronic disease. Physicians should be paid and supported for taking responsibility for assertively coordinating care for patients with complex chronic conditions. Part of that coordina-

tion certainly might involve interacting with nurses and others from disease management vendors.

We should be testing various new payment approaches. There are already limited precedents in the Medicare physician payment system for the kinds of changes that would be needed. In contrast to true prospective payment systems used for other provider types, the physician payment system suffers for being "fee for individual items of service." Yet, renal physicians for many years have received a monthly capitation payment for their professional services for end-stage renal disease. Similarly, Medicare pays for a few "care plan oversight services," e.g., for patients under the care of home health agencies. These small payment precedents should be examined and built on.

Payment models could distinguish how well a medical practice is integrated. For example, solo and other small practices might receive relatively small care management fees that essentially would enable them to better communicate with disease management vendors. On the other hand, larger, more integrated practices would receive larger care management fees and possibly Part B or maybe even Part A payments under some circumstances. This would that permit them to directly manage disease, without the need for a separate third-party organization. The additional payments initially might be focused on care coordination for those patients with multiple and complex chronic conditions, but over time I envision that traditional Medicare might pay some multi-specialty group practices forms of capitation for a much broader range of their patients.

One new payment model has appeared in slightly different forms in Medicare legislation in the past two sessions of Congress, but ultimately lost out to the corporate approach.[7] A token Medicare Care Management Demonstration, Section 649, similar to this approach, survived in the final MMA. It would place on physicians and their staffs responsibility and accountability for clinical care coordination of medically complex individuals. Participating physicians would coordinate clinical care, consult with other providers as necessary, and receive a monthly administrative payment for the extra time and attention involved. The model could be expanded in a number of ways. For instance, physicians could be required to have on staff or under contract a case management function to make referrals to community resources that could address the supportive service needs of these patients.

In addition, CMS has proposed another approach to changing the nature of physician practice—the physician group practice demonstration, which I understand is scheduled to begin next year if the Office of Management and Budget signs off. However, the demonstration is limited to large-group practices that have at least 200 full-time physicians. The physician group would receive bonus payments to the extent that spending is below established targets. This demonstration is on the right track, although it does not target the population with multiple chronic conditions. The size of the physician group would limit how well the model can be replicated if it proves successful. Nevertheless, it is another approach that attempts to change physician payment incentives and reward greater integration of physician practice and, accordingly, it deserves to be as high a priority as the CCI program.

CMS has numerous other demonstrations to test care management and disease management models. However, all of them have design issues that will likely limit their success for medically complex individuals. Several projects target specific diseases, rather than beneficiaries with multiple conditions. And the demonstration models typically ignore addressing the crucial role of the treating physician in care management.

In conclusion, I applaud the efforts of Congress in general and this subcommittee in particular for recognizing the unique challenge posed by the growing number of Medicare beneficiaries living with multiple and complex chronic conditions. The disease management initiatives are a useful response, but, in my opinion, an insufficient one. The traditional Medicare program has the opportunity to pioneer in the area of payment policy, as it has successfully done a number of times in other areas. Working with the willing in the medical community, Medicare can help produce overdue restructuring of the practice of medicine and reorient at least some of the delivery system to chronic care management.

While the MMA provisions are a start, I believe they are overly focused on a corporate, vendor solution—a business platform—for problems in the program that would be served better by involving those who actually deliver health care at the

[7] Most recently, the complex clinical care payment concept was included as a demonstration in the Senate version of the Medicare reform legislation, Section 443 of S. 1, in June 2003. The provision set new standards for physicians willing to participate, including conducting a range of care coordination activities that linked medical and supportive services oriented to the beneficiary and family caregivers.

front line—physicians and other clinical professionals in their own medical practices.

Chairman JOHNSON. So, I thank you all for appearing before us today. I believe that the CCIP is one of the most transformational elements of the Medicare modernization bill, as it challenges all of us to begin thinking about medicine and health care in new ways. I look forward to the testimony of all of our witnesses. Now, Mr. Stark, if you would like to make an opening statement.

Mr. STARK. Thank you, Madam Chairman. I am pleased that we are here today to discuss the CCIP that was included in the bill last year. I must say I am pleased you are having the hearing. It is a tribute to your power and party that you could close an airport to keep my witness from attending, but I bow to political pressures these days all the time. I do know that we will have a chance to hear him, Dr. Berenson, at another time.

The disease management approaches, such as the CCIP, I guess, that use patient coaches, and they can be helpful tools, but I hope we will also get to discuss today the difference between young working people with chronic illnesses and those of us who are older and often have far more, larger, multiple chronic illnesses. I think that it is fair to ask whether our money might be better spent on programs that enable chronically ill patients greater access to physicians rather than rely on corporate vendors that actually kind of remove the patients further from their doctors and funnel money to for-profit disease management companies.

I want to encourage the Secretary to look into the effectiveness and efficiency of these vendor-based programs and to determine their value to Medicare relative to other approaches. I understand that they have been having some success with managed care plans, but a small percentage of our seniors are in those, and I think that we can't overlook the 70 or 80 percent of beneficiaries who rely on a primary care physician. Because of the expense of covering seniors, we have—they are sort out of the employment-based insurance system, and we have the oldest and sickest people in America in our system, the Medicare system. So, approaches that work with younger, healthier problem might not apply to the far more complex situation that we find in many of our Medicare beneficiaries.

I know you have expressed interest in advancing chronic care in Medicare and I think this is an area we could continue to work on. I think we should. I have been working for some time and currently have a bill to provide a comprehensive chronic care benefit in Medicare, and I think that is something we are going to have to work on with physicians to find what a chronic care protocol should be, and can there be one that we can define, as we now do various codes that we use to reimburse physicians.

There are a whole lot of things that I don't think we have the expertise in this Committee to define, but I think we have to encourage CMS perhaps and the various medical groups to come up with their suggestions as to what they think ought to be the physicians' role in this, because I think without them, we may not get the results that we both want. Thank you very much. I look forward to hearing our witnesses.

Chairman JOHNSON. Dr. McClellan, welcome.

STATEMENT OF THE HONORABLE MARK MCCLELLAN, M.D., PH.D., ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Dr. MCCLELLAN. Thank you, Chairman Johnson, Representative Stark, and Representative Crane. It is a real privilege to be here with you today at this critical time for the Medicare program to discuss the new CCIP. This is a major step for us, a new step for us, to improve the care of chronically ill beneficiaries in Medicare fee-for-service; and it is a real privilege to be involved at this time when we are taking so many new steps in Medicare. I want to thank you for your leadership in making this possible.

Medicare beneficiaries living with chronic conditions in the traditional fee-for-service program face a particularly challenging task in managing their conditions. The goal of the CCIP, this program, is to work closely with health care professionals to assist those beneficiaries in using the latest evidence-based management techniques and information technology to get better outcomes.

The widespread failings in chronic care management are a major public health concern today. In my own experience in medical practice, I have often seen doctors and nurses and other health professionals provide high-quality care for people with chronic illnesses in spite of, rather than because of, the systems in which they practice. Yet too often, Medicare beneficiaries do get less than optimal care for their chronic conditions because they have a lot of problems and can suffer if the care is fragmented and if they aren't well informed about how to follow their doctor's treatment plan. Fragmentation leads to poor health outcomes.

Since chronic illnesses account for most of the deaths among Medicare beneficiaries today, this is a big deal for our Medicare beneficiary population. It can also lead to high medical costs. Beneficiaries with five or more chronic conditions represent 20 percent of our population; that is 66 percent of our program spending, and most Medicare expenditures for the care of these beneficiaries are for multiple and often preventable hospitalizations. Currently, our payments are not designed to promote disease prevention and avoid poor outcomes. Instead, as Representative Stark noted, we pay for services that are primarily related to dealing with disease complications themselves, missing opportunities to prevent the complications in the first place.

The new MMA is our best opportunity ever to change the focus to prevention, and the CCIP is an important part of that effort. As my written testimony describes in more detail, chronic care management programs have repeatedly demonstrated an ability to reduce costs while improving health and the satisfaction of beneficiaries.

Many Medicare Advantage health plans have engaged in disease management activities for our beneficiaries in the past 2 years. In one such program, hospital admissions for congestive heart failure were reduced by 70 percent. By preventing these acute complications, the plan saved $3 for every $1 it invested. Lower complications is one reason that Medicare Advantage plans save so much money for beneficiaries of chronic illnesses compared to fee-for-

service Medicare, and that is why it is important for us to make sure that these kinds of plans are available to beneficiaries who prefer them, especially beneficiaries with limited means.

Despite the proven advantages of chronic care improvement programs, however, millions of beneficiaries who are most likely to benefit from them have the least access because they aren't part of fee-for-service Medicare. That is going to change now. As called for under the MMA, the Secretary will enter into agreements with qualified organizations, collaborative groups, including physician organizations and others, to run large-scale regional CCIPs for 3 years using prospectively identified beneficiaries with congestive heart failure, complex diabetes, and chronic obstructive pulmonary disease. We expect that the CCIPs will collectively serve between 150,000 and 300,000 fee-for-service Medicare beneficiaries during this first phase pilot program.

These programs will be evaluated through randomized, controlled independent trials using the best scientific techniques available. We published the notice in the Federal Register announcing this program last month. Completed proposals from potential awardees are due by August 6 of this year, and we expect to implement the first service agreements on schedule by December 8, 2004. We expect the program operations will begin and services will be provided in full by early 2005.

It is important to note in this program that beneficiary participation is completely voluntary and that beneficiaries can get access to the full set of fee-for-service benefits throughout this program. In fact, the point of the program is to help them get the most out of their fee-for-service benefits.

The payment to program awardees will be performance-based. They don't get paid unless they improve performance: performance in quality, performance in saving money for the Medicare Program at the same time. Fees paid to awardees will be at risk for performance improvements in clinical quality, in beneficiary and provider satisfaction, and for reduced costs across their assigned target populations compared to regional control groups.

I want to emphasize again, we fully expect this program to improve beneficiary health outcomes, to increase their satisfaction with the services they receive, to improve the partnership between care givers, health professionals, and patients, and to save the Medicare Program money. It is an innovative model for care delivery, and it is a real pleasure to have the opportunity to be here working with you to implement it. Thank you for your time. I have more detailed written testimony that I would ask be read into the record, and I would be happy to answer any questions you may have.

[The prepared statement of Dr. McClellan follows:]

Statement of The Honorable Mark McClellan, M.D., Ph.D., Administrator, Centers for Medicare and Medicaid Services

Chairwoman Johnson, Representative Stark, distinguished members of the Committee: I thank you for inviting me here today to discuss the new Chronic Care Improvement Program, (CCIP) about which we at CMS are very excited. As you know, this voluntary program was created by Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The CCIP could be a major new step in improving the quality of care for chronically ill beneficiaries under Medicare fee-for-service. I would like to make particular note of the work that

Chairwoman Johnson did to champion this new program and let her know that we believe that her work will make a real difference in the lives of hundreds of thousands of Medicare beneficiaries across the country who suffer from chronic ailments. Today, I would like to address the questions of how the CCIP may help Medicare beneficiaries, and how Phase I will work, including beneficiary selection, payment, and criteria for expanding the program nationwide under Phase II.

HOW CAN THIS PROGRAM BE HELPFUL?

Medicare beneficiaries living with chronic conditions in the traditional fee-for-service Medicare program face a particularly challenging task in effectively managing their conditions. The goals of the CCIP are to assist these individuals utilizing the latest in evidence-based care management and information technology, as well as personal interactions with caregivers to ensure better outcomes. We believe that Medicare may be able to utilize these proven measures not only to improve the fiscal outlook of the program, but also to more adequately assist our beneficiaries in living healthier lives.

Widespread failings in chronic care management are a major national concern. Many of these failings stem from systemic problems rather than lack of effort or intent by providers to deliver high quality care. Medicare beneficiaries are disproportionately affected because they typically have multiple chronic health problems. Fragmentation of care can lead to poor health outcomes. In addition, Medicare beneficiaries with five or more chronic conditions represent 20 percent of the Medicare population but 66 percent of program spending. Most of Medicare expenditures for care of these beneficiaries are for multiple and often preventable hospitalizations.

Congestive Heart Failure (CHF) and diabetes are among the five most common chronic diseases in the Medicare population. According to findings from the 2002 Medicare Current Beneficiary Survey, individuals with CHF, and coronary artery disease represent 21.3 percent of non-institutionalized fee-for-service Medicare beneficiaries and account for 36.8 percent of Medicare expenditures, including treatment for all their health problems. Individuals with diabetes represent 19.4 percent of beneficiaries and 30.4 percent of fee-for-service Medicare expenditures. Beneficiaries with these diseases tend to have complex self-care regimens and medical care needs, that when neglected, or uncoordinated, can lead to complications and acute care crises. The health risks of these beneficiaries depend heavily on how effectively they are able to control their conditions in their daily lives and whether or not they receive appropriate medical care and effective coordination of their care. Efforts to control their conditions successfully may benefit from ongoing guidance and support beyond individual provider settings.

Prevalence rates of diabetes and CHF are even higher among minorities than among all Medicare beneficiaries. For example, as shown in Figure 1, the Centers for Disease Control and Prevention reports that 23.0 percent of black males and 23.5 percent of Hispanic males ages 65–74 have diabetes compared to 16.4 percent of white males and 15.4 percent of all individuals in that age group. Black and Hispanic females in that age group have diabetes prevalence rates of 25.4 percent and 23.8 percent, respectively, compared to 12.8 percent for white females and 15.4 percent for all individuals in that age group. Given these prevalence figures, improving quality and adherence to evidence-based care has the potential to improve outcomes and reduce racial and ethnic health disparities, consistent with HHS' Healthy People 2010 goals.

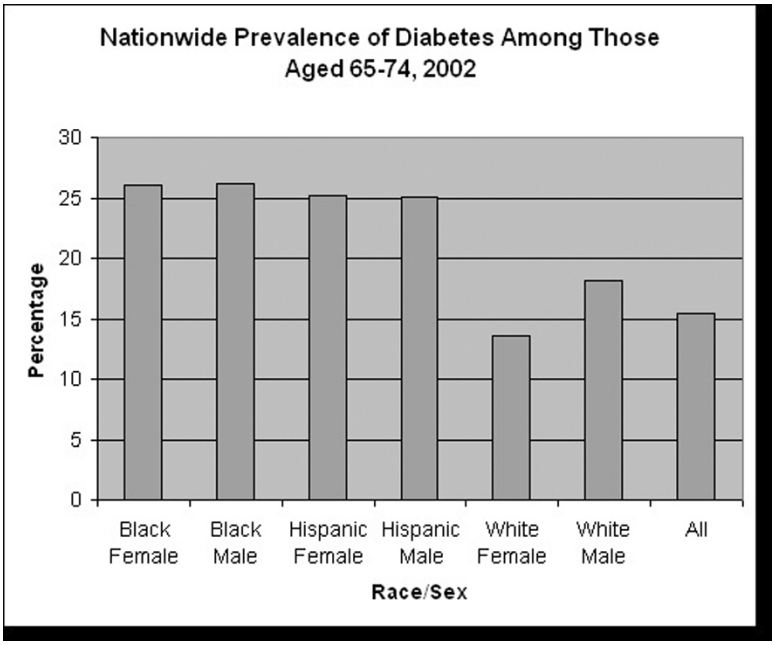

FIGURE 1

The Medicare fee-for-service system is structured and financed to manage acute care episodes, not to manage and support individuals with progressive chronic diseases. Providers of care are organized and paid for services provided in discrete settings (for example, hospitals, physician offices, home health care, long-term care, or preventive services). Patient care can be fragmented and poorly coordinated and patient information difficult to integrate among settings. Providers may lack timely and complete patient clinical information to fully assess their patients' needs and to help prevent complications. Ongoing support to beneficiaries for managing their conditions outside their physicians' offices is rare.

Fragmentation of care can be a serious problem for Medicare beneficiaries. The average Medicare beneficiary sees seven different physicians and fills upwards of 20 prescriptions per year. In a recent survey, 18 percent of people with chronic conditions reported having duplicate tests or procedures and 17 percent received conflicting information from providers.[1] Providers reported feeling ill-prepared to manage chronically ill patients and reported that poor coordination of care led to poor outcomes. Physicians and other practitioners desire to, and often do, provide very high levels of care in this country, but the challenges they face in integrating all of their efforts often frustrate their excellent intentions. As a practicing internal medicine physician I encountered these same challenges. I believe that the CCIP will assist currently practicing physicians and health care providers to avoid some of the challenges that I was faced with while actively treating patients.

The gap between accepted standards of appropriate care for patients with chronic diseases and the care they actually receive is significant. According to findings of a recent national study published in the New England Journal of Medicine, only 56 percent of patients with chronic diseases received recommended care based on well-established guidelines referenced by the researchers. Among patients in the study sample who had CHF, only 64 percent received recommended care, and among those with diabetes, only 45 percent received recommended care. Specifically, only 24 percent of diabetes patients in the study received three or more glycosylated hemoglobin tests over a two-year period. Similarly, in a recent study of practice patterns

[1] Anderson, G. *Chronic Conditions: Making the Case for Ongoing Care*. Partnership for Solutions and the Robert Wood Johnson Foundation, p. 32.

under Medicare, researchers found that, across all States, an average of 66 percent of Medicare beneficiaries with heart failure received ACE inhibitors and 16 percent with diabetes received a lipid test.

A concerted effort to coordinate care and enhance patient compliance will result in fewer acute episodes of care, fewer disease complications and will help eliminate redundant services as physicians and other providers repeat tests and evaluations previously performed because they lack the ability to access results of those services. These changes alone have the potential to generate substantial savings.

Currently, Medicare fee-for-service payments do not encourage prevention of diseases, good outcomes and performance. Instead, the payment system provides money for acute events, missing a potential opportunity to prevent these situations which could be beneficial from a cost standpoint, but, more importantly, from a health perspective. In a sense, payment incentives are the opposite of the way they should be. The CCIP seeks to address this problem, as well as others described above, by rewarding efforts to prevent acute episodes and improve health. Under CCIP, awardees will work to increase patient compliance, facilitate communication between patients and providers, and better coordinate care among providers caring for the same individual. In a much more direct way than ever before under fee-for-service Medicare, economic incentives will be directly lined up with prevention and performance. We hope to reward high quality care, rather than high volume and high intensity care.

Our work with CCIP will nicely complement previous efforts to provide consumers with information on quality outcomes in nursing homes, home health agencies, and hospitals, and to line up economic incentives with quality standards. This shift in payment and emphasis is a demonstration of the Administration's commitment to a coordinated, patient-centered approach to healthcare.

CMS is also working to line up physicians' economic incentives with quality care through such programs as the physician group practice demonstration project that will provide bonus payments for improvements in quality. We also will be conducting a demonstration under Section 649 of the MMA to encourage physicians to promote continuity of care, use established clinical guidelines and prevent or minimize exacerbations of chronic conditions. Additionally, beginning in 2006, all Medicare Advantage plans will be required to operate chronic care improvement programs of their own. These plans will be able to use varying payment methodologies to line up economic incentives with quality care from providers. The CCIP under Section 721, although important in its own right, is not the only tool CMS will be using to assist Medicare beneficiaries with chronic conditions to effectively manage their care.

CHRONIC CARE IMPROVEMENT POTENTIAL

To date, there has not been a sufficient number of thorough tests of whether chronic care improvement will improve health care quality and reduce costs in Medicare. However, private companies have been utilizing the techniques called for under CCIP for some time, and have demonstrated some success in improving health outcomes.

Michael Rich and colleagues found that a nurse-directed multidisciplinary intervention program reduced net cost of care an average of $153 per patient, per month, for the treatment group versus the control group. Readmissions in the control group were nearly double that of the treatment group.[2]

A major U.S. company reported that a disease management program for diabetic patients run out of an on-site clinic realized savings of more than $600,000 in reduced sick time usage in its first year of operation.[3]

Ronald Aubert and colleagues found significant decreases in fasting glucose levels among patients who were provided with the services of a nurse case manager who was also a certified diabetes educator. These patients reported perceived improvement in their health status more than twice as often as their control group counterparts.[4]

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[2] Michael W. Rich, Valerie Beckham, Carol Wittenberg, Charles L. Leven, Kenneth E. Freedland, and Robert M. Carney, "A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure," New England Journal of Medicine, 333, no. 18, November 2, 1995: 1190–1195.

[3] Annemarie Geddes Lipold, "Disease Management Comes of Age, Not a Moment Too Soon," Business and Health, June 19, 2002.

[4] Ronald E. Aubert, William H. Herman, Janice Waters, William Moore, David Sutton, Bercedis L. Peterson, Cathy M. Bailey, and Jeffrey P. Koplan, "Nurse Case Management to Improve Glycemic Control in Diabetic Patients in a Health Maintenance Organization," Annals of Internal Medicine, 129, no. 8, October 15, 1998: 605–612.

Researchers at Geisinger Health Plan found that patients who chose to enroll in its diabetes management program had higher scores on diabetes-related HEDIS (Health Plan Employer Data and Information Set) performance measures and lower average monthly claims. Inpatient days per patient, per year, were lower, though there were more primary care visits.[5]

Another study found that telephonic nurse guidance for CHF patients following initial hospital admission resulted in a 47.8 percent decrease in heart failure readmissions at six months. The authors reported medical care cost savings net of intervention costs.[6]

In another study, readmissions for heart failure were reduced 56 percent in the first ninety days after discharge for high-risk CHF patients age seventy or older.[7]

The Diabetes Care Connection program, implemented in 2000 by the Hawaii Medical Service Association (HMSA), targeted all of its 40,000 beneficiaries with diabetes, including more than 6,000 Medicare beneficiaries. Cap Gemini Ernst and Young found that a much higher percentage of beneficiaries had their blood glucose levels tested during the first year of the program than in the baseline year. Also, total per capita claims costs were lower for HMSA Medicare beneficiaries with diabetes in 2000 than in 1999, mainly because of reduced hospital costs.[8]

Despite these proven successes, Medicare beneficiaries who are most likely to benefit from chronic care management services are unlikely to participate in them because they have been unavailable under the fee-for-service program. Many of the Medicare Advantage health plans have engaged in one form or another of disease management in the past few years. These programs have assisted beneficiaries enrolled in those plans to reap the benefits of more coordinated and effective care management. In one such Medicare Advantage disease management program, their CHF program has produced a 70 percent decrease in hospital admissions. They calculate that for every dollar they invest in their disease management program, they realize a savings of three dollars. In their diabetes management program, this health plan has seen a 45 percent decrease in amputations made necessary by advanced conditions of the disease. New cases of retinopathy have declined by 20 percent among participants in the disease management program. The plan estimates that the 10 year benefit will save $1,500 per patient, or $30 million over that time frame. Unfortunately, the benefits of a disease management program have been unavailable to beneficiaries in the fee-for-service program until now. The CCIP will move toward changing this situation.

The programs cited above resulted in patients who were healthier, who spent fewer days in the hospital and who were happier with the care they received. So what kinds of things do chronic care improvement organizations do to make such a positive impact in people's lives?

Mrs. Jones, a beneficiary with heart failure, was given the option of using a 1–800 number to call and report her weight on a daily basis, or the equipment that would report automatically. If her weight increases by more than a certain amount over a week, her physician would be notified immediately. The weight gain could be an indication that Mrs. Jones is retaining fluid, which could be a reflection of her heart failure flare-up. With such a timely notification, the physician could adjust Mrs. Jones' medication over the phone, or do a simple, quick checkup in the office before a serious complication occurs, saving Mrs. Jones an unpleasant trip to an emergency room or worse.

Another example might be Mr. Smith, a beneficiary with COPD. He could receive home health care on a regular basis to help ensure that his home environment does not exacerbate his condition. Since beneficiaries with COPD often have limited oxygen intake, his home health aid could help ensure that activities such as reaching for a jar from a kitchen cabinet are made easier, that he has air filters in his home,

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[5] Jaan Sidorov, Robert Shull, Janet Tomcavage, Sabrina Girolami, Nadine Lawton, and Ronald Harris, "Does Diabetes Disease Management Save Money and Improve Outcomes?" Diabetes Care, 25, no. 4, April 2002: 684–689.

[6] B. Riegel et al., "Effect of a Standardized Nurse Case-Management Telephone Intervention on Resource Use in Patients with Chronic Heart Failure," Archives of InternalMedicine, 25 March 2002: 705–712. Reported in Health Affairs, Sandy Foote, July 30, 2002.

[7] M.W. Rich et al., "A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure," New England Journal of Medicine, 2 November 1995: 1190–1195. Reported in Health Affairs, Sandy Foote, July 30, 2002.

[8] Hawaii Medical Service Association, a licensee of Blue Cross Blue Shield Association in Hawaii, has a cost-based contract to operate a fee-for-service Medicare plan. Myra Williams, HMSA vice-president, care management, confirmed study findings, also discussed with David Plocher, Cap Gemini Ernst and Young; and with Robert Stone, American Healthways. Reported in Health Affairs, Sandy Foote, July 30, 2002.

or that he has hypo-allergenic bed sheets, for example. These are all simple activities that could send Mr. Smith to the emergency room.

Another example might be Mr. Rodriguez, a beneficiary with diabetes. He could be in need of transportation services to get to the physician. He could have a history of failing to seek diabetic wellness visits due to transportation issues. These could have led to acute exacerbations of his diabetes, where he had to spend time in the hospital. His nurse case manager could help him obtain transportation so he does not miss critical preventive check-ups. These preventive check-ups, such as retinal exams, glycosolated hemoglobin tests, blood pressure tests, foot exams, etc. have documented benefits in preventing acute diabetic crises.

Another example might be Mrs. Johnson, a beneficiary with CHF and depression. She could have had severe problems with medication compliance and general wellness stemming from her depression. A nurse in an IPA could reach out to her on a regular basis, provide self-care support for diet and exercise, and ensure medication compliance. The physician's office could also bring her in for group therapy and schedule preventive check-ups with the physician. The IPA could use an electronic health record to track Mrs. Johnson's progress and communicate with her other physicians.

We expect many CCIPs to rely on innovative uses of IT equipment, including electronic monitoring, records, prescribing and alerts, to help them carry out their programs. These tools, when properly utilized, are tremendously powerful in aiding physicians, pharmacists and other caregivers to provide the best possible care. Individual physicians, nurses, home health agencies and other health providers may utilize electronic records or prescribing systems within their own practices, but it is often a challenge to integrate these systems so that information gleaned by one provider can be available to others who serve the same beneficiary. Part of the CCIP concept is that awardee organizations will work with the beneficiary and through their own innovative IT systems to ensure effective communication between the beneficiary's providers. That sort of overarching view of things is expected to greatly assist these providers in their effort to overcome the fragmented state of care often encountered today. Additionally, we expect that when these individuals see the benefits of this technology they may be more apt to integrate it more fully into their broader practice.

To put it in human terms, patients served by one of these organizations have said the following:

- "[The program] is the best thing that ever happened to me. Thank God for you. Keep up the good work." *E.A. 60 yrs. Lake City*
- "Please keep this program. It helps in many ways. Keeps you on top of your health, and helps you understand what's happening when things do go wrong. Good Program." *P.D. 51 yrs. Titusville*
- "I am very pleased to have someone help me to take better care of myself and my self esteem is stronger knowing others care about me. This program should extend to everyone." *M.M. 58 yrs Palm Coast*
- "The help I have received through your staff and educational material has helped keep me out of the hospital. Thanks a million. I also appreciate your personal phone calls. They are a great help." *D.B. 57 yrs. Pounce de Leon*
- "[The program] nurses have been a great help to me. I feel that with their help I have been able to control my CHF and the notes to the doctor have really helped getting the doctor to pay more attention to my problems and get to me faster when needed." *C.W. 51 yrs. Ocala*
- "My nurse is fantastic. She is very informative and cares about your condition and helps you to get better or take care of yourself as best that you can. She is the best. Thank you for assigning her to me. I feel blessed to know her." *L.G. 35 yrs. Jacksonville*

These outcomes represent the kinds of results we hope to accomplish through the CCIP.

HOW THE PROGRAM WILL WORK

On April 23, 2004, CMS published in the *Federal Register* a notice informing chronic care improvement organizations of the possibility of working with CMS in providing services to Medicare beneficiaries under the new program established by Section 721 of the MMA.

In Phase I, the Secretary will enter into agreements with qualified organizations to run large-scale regional CCIPs for 3 years, for prospectively identified beneficiaries with CHF, complex diabetes, and chronic obstructive pulmonary disease (COPD). There is some evidence that self-care support, education, and other tools targeted at beneficiaries with these conditions are particularly effective at improving clinical outcomes, reducing overall cost, and improving beneficiary and provider

satisfaction. The CCIPs are to be implemented in approximately ten regions where at least 10 percent of the Medicare population resides. We expect the CCIPs will collectively serve between 150,000 and 300,000 chronically ill fee-for-service Medicare beneficiaries. These programs will be evaluated through randomized, controlled trials, with at least 10,000 beneficiaries in the control group for each program. The evaluations will be conducted by an independent entity.

Each program will offer self-care guidance and support to chronically ill beneficiaries to help them manage their health, adhere to their physicians' plans of care, and ensure that they seek (or obtain) medical care that they need to reduce their health risks. The programs will include collaboration with participants' providers to enhance communication of relevant clinical information. The programs are intended to help increase adherence to evidence-based care, reduce unnecessary hospital stays and emergency room visits, and help participants avoid costly and debilitating complications. CCIPs will be required to assist participants in managing their health holistically, including all co-morbidities, relevant health care services, and pharmaceutical needs. CMS will test models that use a wide variety of interventions to bring about improvements in clinical quality, satisfaction and reduced costs.

As intended by Congress, CMS will seek to partner with awardees whose CCIPs are designed to support and improve the patient-physician relationship, not interfere with it. CMS is particularly interested in programs that have a track record of success in, or a comprehensive plan for, engaging beneficiaries' physicians and other providers. Given the considerable time constraints that today's physicians face, we anticipate that physicians will appreciate the timely, actionable information that these services could provide. We also anticipate that physicians will appreciate better-educated patients and better information about what is happening with patients outside their offices. There is nothing about these programs that will supplant a physician's autonomy.

Completed proposals from potential awardees are due by August 6, 2004 and we expect to sign the first service agreements by December 8, 2004. We anticipate that program operations will begin and services will be provided by early 2005.

ELIGIBLE ORGANIZATIONS AND BIDDING

Organizations eligible to apply to implement and operate programs under CCIP include: (1) disease management organizations; (2) health insurers; (3) integrated delivery systems; (4) physician group practices; (5) a consortium of such entities; or (6) any other legal entity that meets the requirements of the solicitation in the *Federal Register*, published April 23, 2004.

The bidding process is designed to allow different approaches to be reviewed in a comparable manner. Applicant organizations will propose the geographic region(s) they wish to serve. CMS will provide applicants with a de-identified nationally representative sample dataset of the type of beneficiaries who would be included in this pilot, on which applicants will base their bids. Finalists will be provided with geographic specific data to enable bids to be adjusted, if necessary, for regional variations.

The beneficiary participation process will be conducted in a way that balances giving beneficiaries the greatest opportunity to participate if they want to, while protecting them if they do not. It is important to note that participation is completely voluntary. Beneficiaries who participate may terminate participation at any time. This program is not a form of managed care, in the sense that it has no gate-keeping function, operating to limit services, or do a pre-service review of appropriateness of care. Beneficiaries will remain enrolled in the traditional fee-for-service program and have access to the full range of Medicare benefits as they currently stand. Additionally, beneficiaries who participate in the program will have access to any participating Medicare provider. The beneficiary participation verification process works as follows:

1. *CMS identifies eligible beneficiaries.* All beneficiaries in a chosen geographic area will be screened for eligibility based on historical claims data. Those beneficiaries who are deemed eligible will be randomly assigned to one of two groups—the intervention group or the control group.
2. *CMS contacts enrollees by letter.* All beneficiaries in the intervention group will be notified of the opportunity to participate through a letter from the Medicare program including the information specified in the legislation. The letter will provide a description of the program and give the beneficiary an opportunity to decline to be contacted by the CCIP organization. The letter will detail how the beneficiary can obtain further information about the program.
3. *If the beneficiary says 'No,'* awardee would not contact beneficiaries who opt not to be contacted regarding the opportunity.

4. *If the beneficiary is silent—awardee attempts to contact beneficiaries to confirm participation.* CMS will then expect each awardee to contact all intervention group beneficiaries in its area who were silent to describe the program and ask if the beneficiary would like to participate. CMS will provide a specific protocol that each awardee must use during the initial contact. With regard to non-responders, we will expect applicants' proposals to specify detailed descriptions about their outreach protocols, including, for example, frequency and number of outreach attempts, and how the applicant will ensure that outreach efforts are respectful of beneficiaries. CMS may negotiate limits on the number and/or frequency of outreach attempts during the outreach period, and may specify that awardees will be required to cease further outreach efforts after the outreach period.
5. *If the beneficiary is contacted and says 'Yes' or 'No,'* the awardee will record the beneficiaries' responses. Beneficiaries who agree to participate will be considered participants until they either become ineligible (for example, joining a Medicare Advantage plan) or notify the awardee or CMS that they no longer want to be contacted by the awardee.

Again, participation is always voluntary. Participants can notify the awardee or CMS at any time that they no longer want to be contacted by the awardee.

Awardee organizations will be responsible for serving an entire population assigned to them by CMS. They will be held accountable for improving clinical, satisfaction, and financial outcomes over the entire assigned population. Because of this fact, the program is considered to be "population based." Awardees are held responsible for beneficiaries who choose to participate in the program, as well as those who choose to not participate. A valid comparison between beneficiaries offered the opportunity to participate in the intervention group and beneficiaries in the control group requires that awardees performance measures include data from intervention group beneficiaries who choose not to participate, since we would have no way of knowing the rate at which beneficiaries in the control group might similarly participate or not.

The CCIP will be set up so that its activities, including contacting physicians with beneficiary health information, are health care operations of Medicare fee-for-service, and therefore, entail permissible disclosures under the Health Insurance Portability and Accountability Act (HIPAA). Health care operations, allowed under the HIPAA privacy rule, include population-based activities relating to improving health or reducing health care costs, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives, and other related functions. Furthermore, CCIP organizations would be considered business associates of CMS, and therefore it would be permissible to transmit health information to them.

PAYMENT

The CCIP contracting model is flexible enough to accommodate a wide range of program models, but payment methods in all instances will be performance-based. Fees paid to awardees will be at risk for performance improvements in clinical quality, beneficiary and provider satisfaction, and reduced costs across their assigned target populations compared to their regional control groups. The statute purposely links payment and quality. The underlying premise of the CCIP initiative is that through performance-based contracting, improvements in quality will lead to better financial, health, and satisfaction outcomes

As a condition of continued participation in the CCIP, organizations will be required to demonstrate improvements in quality of care for beneficiaries in the intervention group. Prior to award, the specific measures for improved quality and satisfaction will be negotiated with the organizations based upon the quality parameters listed in the solicitation as a minimum. CMS reserves the right to reduce or withhold payments should the mutually agreed upon quality targets not be achieved. The specific guidelines for such action will be negotiated with each organization prior to award.

The goal of the CCIP is to reduce Medicare costs in traditional fee-for-service, while simultaneously improving beneficiary outcomes. CMS is requiring a guaranteed minimum of 5 percent savings to the Medicare program, including all CCIP fees for the assigned population compared to the control group's experience. The exact amount of savings is contingent upon a number of unknown variables such as the total number of sites and beneficiaries who will be served across the program and whether CMS will receive and accept proposals with more aggressive savings guarantees.

As part of the application process, all organizations will be required to show proof of their financial solvency and ability to assume financial risk up to 100 percent of

their monthly fees, up to the 5 percent net savings guarantee. The agreements between CMS and the awardees will specify the exact mechanism for guaranteeing performance and security. Their ability to achieve proposed Medicare savings targets will be evaluated on an individual basis based upon their proposed program designs, the results of site visits, and evidence of prior achievements. CMS plans to hold a bidders conference on May 13 for organizations interested in providing CCIP services under this new program. The conference will provide participants an opportunity to gain knowledge of issues associated with applying to implement and operate a chronic care improvement program as part of Phase I of CCIP. CMS has already enrolled as many potential bidders as it can to attend the conference.

EXPANSION OF THE PROGRAM

Phase II, the potential expansion phase of CCIP, depends on the success of Phase I. The statute provides for the Secretary to expand successful CCIPs or program components, possibly nationally. The Secretary may begin Phase II expansion not earlier than 2 years, and no later than 3‡ years, after implementing Phase I. Quality and satisfaction measures will continue to be a key part of contracts with CCIP awardees through Phase II.

CONCLUSION

We at CMS fully expect this program to improve beneficiary health outcomes, increase their satisfaction with the services they receive through Medicare, better the partnership between caregivers and patients, and save the Medicare program money. It is an innovative model for care delivery, focusing on preventing problems, rather than allowing them to develop in the first place. We appreciate the Congress' support in providing the means for this program to take place and look forward to sharing the results with you as it progresses. Thank you for your time and I would be glad to answer any questions.

Chairman JOHNSON. Thank you, Dr. McClellan, for your testimony and your written testimony, which was very useful. Could you enlarge somewhat on the demonstration under section 649 where you have the chance to encourage physicians to promote continuity of care?

Dr. MCCLELLAN. That is another program that we are undertaking to achieve the same goals, improving quality at a lower cost. That is a demonstration program, because some of the techniques that we are going to implement there, such as more direct payments for performance to physicians and the like, have not been as well evaluated yet as some of the disease management and care management that will be part of the CCIP.

So, that is a demo program that can help us with complementary approaches to get at the same goal, getting better outcomes to beneficiaries at a lower cost by supporting and encouraging providers to prevent complications in the first place. I think it can complement here what we are doing here well. That demonstration is still under development internally, and we will have more to say about that in the coming months.

Chairman JOHNSON. Thank you. I hope it will allow smaller physician practices to participate, because I do think the issue, at least in developing this part of the law, was very unclear to us. I think it is still unclear how much of this function of management can be integrated into standards of practice for individual specialties, and we need a better handle on that as we move forward so that we only employ a coordinator where a coordinator is necessary, perhaps across specialties or whatever.

A lot of what we are talking about should be part of the next round of physicians' standards of practice. Therefore, this whole issue of chronic disease management is going to be present as we

deal with one of our other responsibilities that we have from the passage of the MMA, which is to rethink of how we pay physicians or we will be able to pass real reform under the physician payment section of the Medicare law.

So, as we think about how we are going to change how we pay physicians, we need to think about the fundamental flaw in the Medicare Program, which is that it is acute episode focused and not focused on what really has become the challenge in medicine, which is to prevent the development of acute episodes.

So, in that framework, there were a number of interesting comments by Dr. Berenson in his testimony. One of the briefer ones that he mentioned was they need to look at not just randomized controls, but matching, to allow smaller entities to compete in the trials. Do you have a comment on that?

Dr. MCCLELLAN. We are using randomized approaches in this pilot program that was actually mandated by Congress, as you know, in the MMA. In many of our demonstration programs, however, we rely on other techniques to identify what the effects of a particular program might be. In some settings where it is not feasible to do randomizations, which might be the case involving small physician groups, matching may be a good alternative. I do want to try to take further steps to be able to implement steps, implement methodological approaches even in smaller settings. I would emphasize these CCIP programs are not going to succeed if they don't work well with physician offices.

Most Medicare beneficiaries get their care primarily through small physician groups; and because you have to improve the outcomes for a population in order to get the performance reward in the CCIP program, therefore, the groups are going to have to work well with these small physician offices, even in the CCIP. I think we can learn something from this effort and from the randomization techniques used here, about what works well in small physician groups, that can carryover to the broader goals you mentioned about improving our payment systems to physicians.

Chairman JOHNSON. In your RFP, are you very specific about how that project should relate to physicians?

Dr. MCCLELLAN. We are very specific in emphasizing that we expect these programs to work well with physicians and other health professionals. In my own experience in dealing with a variety of disease management programs, the ones that I found to be most helpful were the ones that supported my work, the ones that reminded my patients that they needed to come in for a follow-up exam or to get another laboratory test done, or the ones that helped my patients identify when they were having complications early before they got to a very serious stage, such as a little bit of weight gain in patients with heart failure, so they could come into the office if necessary and get that complication headed off. Those kinds of steps are built into this program, and we are backing it up by including provider satisfaction measures as part of the formal evaluation. The payments to these organizations that participate in CCIP will depend on how well they do with doctors and other health professionals.

Chairman JOHNSON. Thank you. So, you will be evaluating that particular piece of the connection and the motivation for phy-

sician involvement as you determine which of all the really many proposals you will select. I am pleased, what a tremendous response you are having for the informational seminar that is coming up this week.

Dr. MCCLELLAN. It is tomorrow. We are oversubscribed. The auditorium at our headquarters in Baltimore is going to be full. We have more than 550 participants, and they span the spectrum. It not only includes disease management business, but also includes a number of physician group organizations, a number of academic medical center organizations.

We have a very broad range of participants, and in many cases, I expect these different groups will be working together in order to serve the whole beneficiary population, which includes a lot of patients that are treated by small physician groups, includes a lot of patients with disabilities, cognitive impairments and the like. Again, you can't do well on the performance measures unless you do well for all of these groups.

Chairman JOHNSON. Are you having sufficient interest from those States that have geriatric centers to participate in that demo, where we want to look at how a geriatric center would pair with physicians, for example, in rural areas so we can look at physician performance, small office performance in this context?

Dr. MCCLELLAN. We are going to include rural areas and geriatric programs that work with our rural providers and rural beneficiaries in this effort. As you know, there are other demonstrations and other initiatives in the MMA that are also targeted at geriatric research programs and geriatric programs in rural areas as well, so that will be part of this overall effort to learn more about how we can help doctors and other health professionals improve the quality of care for their patients.

Chairman JOHNSON. Thank you, Dr. McClellan. I reserve the rest of my questions. Mr. Stark.

Mr. STARK. Dr. McClellan, first of all, welcome to the Committee. I am puzzled just by a couple of things; and as a physician, you can help me here. I don't—and this is how a patient might react and a physician might react, but it seems to me, as I have read through this, that there is nothing—if I am under care or going to an internist and I think of the internist as my doctor, okay, and I develop diabetes or high blood pressure and a bunch of different things, I will be contacted in one way or another by CMS. Will I get a letter or phone call?

Dr. MCCLELLAN. You would initially get a letter from CMS that will inform you that you have the option to participate in this program.

Mr. STARK. Will it reference my doctor at all?

Dr. MCCLELLAN. The initial contact won't. It will be based on beneficiaries.

Mr. STARK. I would probably run to my doctor, right? I might say, what is this? First of all, I would be a little curious as to how you knew I had all of these problems, but—and that is a question of privacy that I want to get to in a minute. It is my understanding that this—the provider, the company or the corporation that is going to do this management, is going to try and entice my physi-

cian into cooperating, but not necessarily pay him or her anything for doing anything; is that right?

Dr. MCCLELLAN. The plans or the organizations that support these programs are going to have a hard time succeeding if they don't have buy-in from that internist that you mentioned.

Mr. STARK. How are they going to buy in? Are they going to pay the doctor something?

Dr. MCCLELLAN. They don't necessarily have to pay directly, but they do need to make clear to the physician why this is in their best interest to participate, and it is to make sure——

Mr. STARK. As a practicing physician, would it be a fair statement to say that physicians as a general rule—I won't put this in order—but somewhere between "resent" and "rail against Congress" for interfering with their practice, CMS interfering with their practice, Blue Cross interfering with their practice, nurse practitioners telling them how to practice, or pharmacy detail people telling them how to do their practice. They tend to be relatively independent folk. How is my doctor going to react when some corporate guy calls them up and says, why don't you check up on Stark and make sure he is losing weight and not smoking and doing all those things? I have a disconnect there that I think could be problematical from the physician standpoint.

Dr. MCCLELLAN. Speaking as one of them, what I found most frustrating is when I was contacted by many of the types of individuals you described who were telling me to do something that I thought was not in the best interest of my patient. At other times, I have been contacted by disease management organizations, patient advocates and others who had some very helpful things to say, some things that I found useful in improving the care that my patients got and doing it in a way that helped me.

Mr. STARK. I would understand how this would work if Kaiser decides to do it, and Kaiser Permanente tells all the doctors in their group, we are going to do this and we are going to cooperate, because they are all on salary. I have one other question, and that is a little bit off the topic, but we had some problems last year on estimates from the actuaries. Both you and Secretary Thompson have promised us publicly and in private to reinstate our access to the Office of the Actuary. Does that still stand?

Dr. MCCLELLAN. We have both promised transparency in working with the actuary and access to estimates that you need.

Mr. STARK. We have a couple of analyses at this point that we understand are completed. These are previous requests, not new work for them, that we understand are complete and are not being released. Would you get them to release those studies?

Dr. MCCLELLAN. If you will send me the details, we definitely want to pass along final results.

Mr. STARK. I hate to beat a dead horse. I didn't mean Secretary Scully as a dead horse. Thank you, Madam Chairman.

Chairman JOHNSON. I would like to recognize Mr. Crane, a diligent Member of our Subcommittee, always present at our hearings. Thank you very much.

Mr. CRANE. Thank you, Madam Chairman. Dr. McClellan, the goal of this new program is to reduce Medicare costs while also improving beneficiary outcomes. Do you believe that Phase I of the

new CCIP, will meet both of these goals? If so, how much do you estimate Phase I will provide in savings to the Medicare Program?

Dr. MCCLELLAN. I do think it will meet both of the goals, that performance contracts that we are setting up envision a 5-percent reduction in costs. Some of these programs that I mentioned in my oral testimony have achieved far larger savings than that.

To stay on the conservative side, our actuaries have estimated a 1-percent cost savings for all of the beneficiaries that will be involved in this program, but that is an important savings if we are achieving better health results at the same time. So, we are going to wait and see. The reason we are doing this as a pilot is to see which methods work best, and we can get the maximum savings and the maximum improvements in outcomes.

Mr. CRANE. We all know that preventive health care services save the Medicare Program money, but it is often hard to track the savings of providing these services. I imagine it will be difficult to quantify the savings from the new disease management initiative. How will the CCIPs be evaluated and measured to ensure that they are improving clinical outcomes and actually reducing costs?

Dr. MCCLELLAN. It is hard to get a handle on the actual impact of things that we do on outcomes, but that is why I appreciate the foresight of Congress in this case, asking us to do a randomized, careful study where we have two populations of patients, one population that gets access to this new pilot program and the other population which is from the same area and has exactly the same kind of characteristics.

We are going to compare the outcomes for those populations, not just look at the people that a disease management program manages to sign up, a chronic care improvement program manages to sign up, but the whole population. We will compare those outcomes with the control group, and based on what I have seen of successful chronic care improvement programs, we should be able to see some improvements in outcomes in a pretty short timeframe.

Some of the programs that have been implemented already to reduce complications from diabetes or heart failure pay for themselves more than one time over within a matter of months in terms of avoided hospitalizations with complications of the disease. So, we will be watching that very carefully and will be reporting to you along the way about how the programs are doing.

Mr. CRANE. Critics have asserted that the CCIP initiative is removed from the physician and that the program does not promote a relationship between the patient and his or her doctor. Can you respond?

Dr. MCCLELLAN. I think we are going to make sure that these programs do have elements that encourage an effective relationship between patients and providers. Those relationships are strained today as many Medicare beneficiaries are seeing more doctors than ever before. A Medicare beneficiary, on average, sees seven physicians in a year, and there is a lot of evidence out there that Medicare beneficiaries are not getting the best possible evidence-based care for their chronic illnesses.

So, there is a lot of room for improvement, and I think some of the main ways that improvements can occur are ways that physicians may well appreciate, like having services that remind pa-

tients when they need to follow up with their physicians and helping patients understand their disease so they will understand why it is so important to comply with the treatment plan that their physician has provided for them, as well as taking steps to help beneficiaries spot complications from their diseases early, as I mentioned before, when their weight is up a little bit, when their blood sugar levels are off a little bit, rather than down the road when they get into costly complications requiring hospitalizations.

All of these steps may actually increase the amount of contact through appropriate office visits with physicians. The difference is, the physicians will be seeing the patients to prevent the complications rather than seeing the patients after the complications have occurred. So, in short, we will be getting much more for our money, and physicians will be able to get much more out of the time that they spend with patients. This is going to be a challenge, and we will be watching closely how well we do and why we will be evaluating these programs in part based on the satisfaction that providers have with the services being provided.

Mr. CRANE. Thank you, Dr. McClellan. We look forward to working with you.

Chairman JOHNSON. Dr. McClellan, to follow up on that point, since it has been so frequently raised, why not just develop a code that shows what you need to coordinate and just change Medicare to pay doctors?

Dr. MCCLELLAN. Well, first, we are paying doctors more. That was another set of provisions in the MMA; it is very important for access to high-quality physician care in this country. I think there are some further steps we can take to figure out whether there are better ways to pay doctors.

As you mentioned in your earlier questions, we have other demonstrations going on and a lot of interest in CMS right now in developing appropriate pay for performance methods where you do get paid more for delivering higher-quality results, for providing better care and not just for having more visits and, in effect, more complications leading to higher payments. So, we will keep looking at the best ways to do this.

The advantage of these CCIPs is that, I think, they are appropriately at a stage where they can be piloted on a large scale and then used on a large scale. There are proven approaches in these chronic care improvement ideas that can potentially have a large-scale, positive impact for beneficiaries.

I think we will learn more along the way in this program and in other demonstration programs about other ways which we might want to improve the payment system, but I don't think it is a question of paying more under the current system. I think it is a question of how we can develop the best evidence to guide modifications through our payment system to get better outcomes at a lower cost. Chronic care improvement is one valuable way to do that; and I think there are probably others, and we will keep pursuing them.

Chairman JOHNSON. It is my hope that out of the combination of pilots and demos that are in process, and others that you have the authority to develop, that we will be able over time to sort out this issue of how much can be integrated into individual physician practice standards and payments, and at what point there is a ben-

efit and a real value added to having a coordinator across specialties or across community-based support programs versus traditional medical support programs. So, I think we need to keep our eye on that ball, how much this can be ultimately implemented through physician payment structures involving coordination of care and how much needs to go beyond that, what kinds of patients need more assistance in that. That leads me to my last question.

Almost all of the chronic programs involve a greater level of patient involvement, patient knowledge, patient education, patient management, and for a patient with dementia, this is hard. We were conscious of that in writing the bill. We do mention the issue of dementia and have some demonstrations that are working specifically on this issue of how do you manage disease management with a patient that has dementia. So, that is an issue raised by Dr. Berenson as well as one that we worked a lot on. Would you talk a little about that in the context of these pilots?

Dr. MCCLELLAN. First of all, at a broad level, we need to be preparing for dealing with dementia issues on even a larger scale. As we are getting better treatments for many other diseases, more and more of our beneficiaries are living longer. Until we get truly effective treatments for dementia, this is going to be an important and probably growing part of our patient population, and dealing with it effectively is an essential part of providing high-quality care to all of our beneficiaries and doing so at the lowest possible cost.

You mentioned a number of demo programs; also, Medicare Advantage programs are going to be specifically targeted to these types of populations, building on successes that we have already seen in particular instances. That is an important part of our response.

I would highlight that in the CCIP itself, the program participants are going to be required to cover and improve outcomes and reduce costs for a whole beneficiary population. They don't get to cherry-pick the healthy beneficiaries. They don't get to target their interventions only at beneficiaries without dementia, without other kinds of cognitive impairments or other types of impairments that might make them harder to work with in terms of the standard management of care approaches.

So, they will be evaluated on performance for improving outcomes for these segments of our population, and if they don't improve it, then they are not going to get the financial rewards, they are not going to be selected to expand coverage more broadly. We are absolutely committed to make sure these chronic care improvement services work for all, for our increasingly diverse population of beneficiaries, and that means effective techniques to work with people with Medicare who have cognitive impairments as well.

Chairman JOHNSON. Thank you very much, Dr. McClellan.

Mr. STARK. Dr. McClellan, could I deal with some concerns on privacy? Let's assume that I start out with one of these organizations, and then I decide I want to quit. What happens to my medical information that that chronic care group would have? Is it protected?

Dr. MCCLELLAN. It is protected. The CCIP information is part of Medicare operations, and it is protected as part of our Medicare-specific activities. It doesn't continue to be available.

Mr. STARK. Once XYZ corporation has my medical records and I decide not to continue participating, what happens to those? How am I guaranteed that they won't sell them?

Dr. MCCLELLAN. The same Health Insurance Portability and Accountability Act 1996 (HIPAA) (P.L. 104–191) protections apply to these records as applied to other confidential medical information.

Mr. STARK. Why aren't they a covered entity instead of a business associate? Covered entity, they could be subject to fines if they misbehaved.

Dr. MCCLELLAN. They are covered in the sense that they are part of our business operations.

Mr. STARK. Stop a minute. You could either be a business associate under HIPAA or you could be a covered entity, a provider. A covered entity has stricter disclosure regulations and more severe penalties for violating those. Why wouldn't these groups be a covered entity?

Dr. MCCLELLAN. If they use confidential medical information improperly and share it outside of the Medicare operations, they are subject to HIPAA sanctions and penalties just like anyone else who uses our Medicare information inappropriately.

Mr. STARK. My staff tells me that there are two classifications. If they are classified as business associates, the violations are not as tight and the penalties are less severe than if they are, in fact, a provider or covered entity. By putting these activities under, quote, "health care operations," it is my understanding that beneficiaries don't need to give permission for their information to be shared nor can they track the sharing of information. So, there are some highly technical things in there that I hope you can look at.

Dr. MCCLELLAN. I want to get that right and do want to emphasize that as business partners, they are subject to the HIPAA rules for business partners. If a beneficiary at their option decides not to participate in this program, they won't collect any more information, in the first place; and even for those beneficiaries that do participate and stay in the program, they are subject to the same HIPAA rules that apply to our health care providers and others involved in our business operations. I do want to work with you to make sure we address this effectively, so that confidentiality and security is a very important part.

Mr. STARK. So much for my questions; now my free advice. The Chair has discussed the idea of how we would reimburse physicians, and the only thing I can think of—and maybe you know of others—is with end-stage renal disease, that the dialysis and the drugs are paid for on a schedule.

There is a capitated fee to the physician to supervise this end-stage renal patient. I don't know how it is designed or how the payment was arrived at, but ought we not to look for something in this chronic care that parallels that? It doesn't cover the tests that they made and everything, but it is kind of a global fee—I am not sure "capitation" is the right word—that the principal or primary physician would receive for checking up on the patient and doing the extra work. Would that make sense?

Dr. MCCLELLAN. I think any proven steps that move toward paying for what we really want, which is better outcome for pa-

tients and then giving the doctors the flexibility they need in this era of very modern and complex medicine, to provide that care as effectively as possible, that is a step in the right direction. I think the question for us is, how do we develop better evidence on whether those models can work?

The capitated payments to dialysis organizations are a bit different than trying capitated payments for doctors and small groups who treat a very diverse range of Medicare patients. The small-group doctors may not be in as good a position as the dialysis organization is to provide those supportive services themselves. They may be better served by working with organizations like the CCIP organizations. I don't know, but we are going to find out more about that.

They may not want to bear the financial risks that come with those capitated payments. They are not in as good a position to have a predictable idea of what their costs are actually going to be for providing high-quality care as the dialysis organizations are. There are some challenges there. I agree with the goal that we need to be pursuing all the steps we can to learn about what really works in paying for performance and giving health professionals the support they need.

Mr. STARK. How many years is it going to take—2, 3, 5 years?

Dr. MCCLELLAN. The CCIP program is going to be a 3-year pilot, but we will be evaluating it before then.

Mr. STARK. My worry is that they are not going to participate if they don't get paid.

Dr. MCCLELLAN. There is a surprisingly large amount of interest from many medical group associations, medical doctors, and others that come in to talk to me about wanting to focus more on the bottom line of improved patient outcomes. So, I think there is more interest there than before.

This is by no means the only approach that we are taking. I think you are seeing, across the board, more interest than ever in CMS, more efforts than ever to develop better quality measures, to try out demonstration programs for what can work, and giving doctors the incentives and support they need to provide better care. So, this program will be an important part of finding the answers. This is an urgent question and I would like to work with you.

Mr. STARK. I think we should let the doctors do it. You guys should come to us and say, we don't know all the words. We can't talk Latin. I think just as we did in the Resource-Based Relative Value Scale, let the doctors come and say—look to do this type of protocol. It might be one, two, three, four chronic diseases. If you have five rates higher, we will have to check this and respond to the CCIP person, and we will have to order tests and check up on the patient, and we think in the course of the year, it will take this much involvement, and set a fee for them.

Let them come up with it, and you guys can bargain. If the doctors don't design it, they are going to resent us telling them what they ought to charge for a new kind of way to practice. I would encourage us to ask the physicians to come and see what they think would be a fair relative to other procedures that they provide.

Dr. MCCLELLAN. I agree with you about getting physician input. I think we can learn a lot from health professionals about

the best ways to meet our policy goals, and we have a lot in already and have heard a lot of good ideas about how to do a whole range of new initiatives successfully, ranging from e-prescribing to management programs to the section 649 and section 646 demos. You name it. There is a lot of physician interest out there, a lot of health professional interest that we can build on, and I intend to keep working with you all to do that.

Mr. STARK. Thank you.

Chairman JOHNSON. Thank you very much, Dr. McClellan. I think this issue of what portion of disease management can be supplemental to a physician action and what portion of disease management needs to cut across a larger swath of medical activity than any one individual physician would be prepared to manage is something we will learn from the demos and the pilots that we have out there. It is a very important issue.

We are going to learn something more about how we reimburse for coordinated care as we work through the challenge of reimbursing oncologists and chemotherapists for cancer care. We have tried to, but not successfully, so, we have some example of trying to reimburse for better coordination of care for a bundle of services. In some places we have succeeded, and other places, we have failed.

I appreciate it and I am delighted to have you as CMS Administrator and the experience that you bring to the table. It is extremely important to us achieving the kinds of goals that Pete and I and other Members of the Committee have.

In closing, I just want to recognize David Kreiss, who has done so much work on this section of the law and, furthermore, who has worked so constructively and progressively and openly with the disease management experts, with disease management companies, with physicians themselves, and with a whole array of people over several years to get the base for these pilots broadly established. I thank him for his constancy and his work.

I thank you for your intense interest in it and this tremendous step forward as you put out these RFPs. We will follow carefully the progress of the project and we will all learn a lot from it. We hope you will work closely with us as we look at the issue of physician payment and see if there aren't steps forward we can make, away from the old acute care, incident-oriented, test-oriented payment structure of current Medicare toward a more holistic approach.

I think physicians are much more interested now than they were a few years ago. I see that out there. That is what they ask you about. That is what they want to know. They are beginning to say, why are you so out of touch with what it is we are now trying to do? Thank you for your testimony and thank you for the good work of you and your staff.

Dr. MCCLELLAN. Chairman Johnson, it is really a pleasure working with you. I want to thank you especially for recognizing David Kreiss and the rest of the CMS staff. They have done a terrific job in putting together a very innovative approach.

The biggest pleasure of this job for me in the month I have been there has been the enthusiasm and the talent and, really, the experience and expertise of the staff in taking these new opportunities we have to do a much better job of delivering high-quality, person-

alized care to all of our beneficiaries. It is going to be a real pleasure working with you.

Chairman JOHNSON. We will invite the second panel up: Christobel Selecky, President-Elect and Chair of the Disease Management Association of America; Dr. Janet Wright, the Medical Director of Cardiology for the Enloe Medical Center of Chico, California; Vince Bufalino, Dr. Bufalino, a member of the Expert Panel on Disease Management of the AHA from Naperville, Illinois. As I say, we will respect Dr. Berenson in his absence, but continue to work with him when next we have a chance to meet with him. Dr. Selecky.

STATEMENT OF CHRISTOBEL SELECKY, PRESIDENT-ELECT AND CHAIR, GOVERNMENT AFFAIRS COMMITTEE, DISEASE MANAGEMENT ASSOCIATION OF AMERICA

Ms. SELECKY. Thank you, Chairman Johnson, and thank you for the promotion. I am not a doctor and I don't play one on television. I would like to thank you very much for inviting me to appear here. As you know, my name is Christobel Selecky. I am the President-Elect of the Disease Management Association of America, which is a nonprofit, interdisciplinary association dedicated to the advancement of health improvement for people with chronic disease. I also am the Chief Executive Officer (CEO) of LifeMasters Supported SelfCare, which is a 10-year-old, privately held disease management organization that provides coaching, education, and support to more than 300,000 people with chronic disease nationwide.

The fact that our health care system does not adequately care for people with chronic disease has been well documented. When chronically ill patients do not receive the right treatment for their conditions, they get sicker and end up in the hospital; and this not only results in poor quality of life for the beneficiaries, but it costs our taxpayers and our health care system a great deal of money.

This gap in care occurs because patients are inadequately trained to manage their illnesses and rushed practitioners do not always have the time, information, and systems to follow evidence-based guidelines and to follow up with their patients and other health care providers. The care gap is particularly acute among our Nation's seniors in traditional Medicare. Prior to last year's MMA, recommended solutions to this problem were piecemeal, incremental, and measuring their impact on cost containment and quality improvement was difficult, if not impossible.

Fortunately, the MMA has created a framework for transforming chronic care in America. Most notably, section 721 will make large-scale, population-based disease management available to beneficiaries in traditional Medicare. In the first phase, financial savings, quality improvement and satisfaction are guaranteed. This approach represents real innovation and an opportunity for Congress and CMS to support delivery system change and outreach to chronically ill beneficiaries.

Disease management programs work. My company, LifeMasters, provides services to a population of mostly aged, blind, and disabled fee-for-service Medicaid beneficiaries in the State of Florida. Over a 2-year period, we were able to reduce total health care costs

by $12.6 million on a population of just 3,500 beneficiaries with congestive heart failure and co-morbidities of Chronic Obstructive Pulmonary Disease, coronary artery disease, diabetes, and mental illness. This represented a 5.6-percent net cost savings to the State of Florida.

This group also experienced a 38-percent reduction in hospital days, significant improvements in evidence-based care, and made significant lifestyle changes as well. I do want to say, too, physicians were actively involved in this program. In a survey we recently conducted, 89 percent of them said they would very highly recommend this program to their colleagues.

These outcomes are typical of disease management programs. Extrapolating these savings to the Medicare CCIP, this could save billions of dollars to our health care system while improving the quality of life for millions of beneficiaries. There are many models possible under MMA, and CMS has encouraged consortia to apply for pilot projects. I would like to describe how a couple of these different kinds of consortia might work.

A multispecialty medical group with sophisticated information technology and established disease management programs could contract directly with CMS. They might subcontract with a call center to do the outreach and enrollment function, but they would perform all of the chronic care improvement functions on their own.

A health plan might contract with CMS and either provide the disease management services themselves or subcontract with a disease management organization. The health plan could provide high-risk case management and home health services, and they could also work with its physician network to develop physician incentive programs to reward active engagement in the program.

A disease management organization could contract directly with CMS for a program. It would provide all of the standard disease management services and could subcontract with the home health agency, a biometric monitoring company and a high-risk case management company if necessary. At the local level, the disease management organization could also identify and develop relationships with community organizations devoted to providing services to seniors.

Finally, a pharmacy benefit management company that is planning on being a prescription drug provider under the new drug benefit could partner with an entity that has an established disease management program. The pharmaceutical benefits manager could use per-member per-month payments from CMS to both cover the disease management costs and possibly even to fund a modified drug benefit that would start before the 2006 start date and also provide an integrated medication therapy management program.

I would like to close with a few recommendations that I hope might help improve the effectiveness of this valuable program. Congress should support CMS with sufficient resources to build the infrastructure necessary to administer and monitor this program. Second, in order to ensure consistency and a standard level of quality, the Administration should consider accreditation by one of the major accrediting bodies or at least a minimum set of quality criteria as a threshold for contracting.

Third, because the goal of Phase I is to identify models that can be successfully used nationwide, in Phase II, the Administration should ensure that models selected in Phase I have proven outcomes and can be scaled to take care of millions of people.

Fourth, in order to more quickly realize financial savings and ensure equitable and consistent measurement of results, the Administration should consider implementing all of the pilot programs simultaneously. Fifth, Congress and the administration should be open to expanding the program earlier than currently specified when the results begin to show expected cost savings and quality improvement. Finally, Congress should consider the implementation of disease management programs whenever you take up Medicaid reform.

In closing, I would like to express my sincere appreciation on behalf of the entire disease management community to you, Chairman Johnson, and to the entire Committee, Chairman Thomas, Secretary Thompson and the leadership and staff at CMS, for making these important services available to the millions of seniors with chronic conditions who need the support to help them live a better quality of life. Thank you.

[The prepared statement of Ms. Selecky follows:]

Statement of Christobel Selecky, President-elect and Chair, Government Affairs Committee, Disease Management Association of America

I would like to thank Chairman Johnson for inviting me to speak before the Committee today.

My name is Christobel Selecky and I am the President-elect of the Disease Management Association of America, a non-profit, interdisciplinary association dedicated to the advancement of health improvement for people with chronic disease.

DMAA's membership comprises the spectrum of entities that have an interest in the advancement of chronic care improvement:

- Healthplans and insurance companies;
- Disease management organizations;
- Academic institutions;
- Integrated delivery systems;
- Physician group practices;
- Employers;
- Monitoring and information technology companies;
- Pharmaceutical benefit mangers (PBMs); and
- Pharmaceutical companies

I am also the CEO of LifeMasters Supported SelfCare, a ten year old privately held Disease Management Organization that provides coaching, education, and support to more than 300,000 chronically ill individuals nationwide.

The fact that our healthcare system is not set up to adequately care for people with chronic disease is well documented. In its landmark report, Crossing the Quality Chasm, the Institute of Medicine (IOM) gave us a roadmap for the creation of a new health system for the 21st Century—a system that is patient centric and focused on closing the gap—the chasm—between best practice and actual care received. This gap was discussed in a well publicized study published just last year in the New England Journal of Medicine[1] in which it was reported that people with chronic conditions receive recommended care only about 50% of the time.

When chronically ill patients do not receive the right treatment for their condition, they end up getting sicker and winding up in the hospital—sometimes when it's too late to help them. This not only results in poor quality of life but also costs our healthcare system—and ultimately the taxpayers in the case of Medicare—more money.

The gap between actual and recommended care occurs because patients are inadequately trained to manage their illnesses, rushed practitioners do not always have

[1] McGlynn, Asch et al, The Quality of Health Care Delivered to Adults in the US NEJM 2003; 348:2635–48.

the time or information to follow evidence-based practice guidelines, and systems don't exist at the provider level to actively follow-up with their patients and other care providers to ensure the best outcomes. Our delivery system needs to change toward the Chronic Care Model described by Ed Wagner and others. But most physicians are operating in 2–3 person offices without resources, platform or staffing to achieve this—it costs a lot of money to build these capabilities—money that most physician practices simply do not have access to.

The IOM recommended using sophisticated information technology systems to facilitate the conscientious, explicit, and judicious use of current best evidence and knowledge of patient values by well-trained, experienced clinicians. The goal is to integrate a fragmented system by building strong information pathways between all the stakeholders—patient, physician, family members and caregivers, and payors and facilitating a team approach. Information technology provides the platform to create that integration.

Fundamentally, disease management is the platform that can facilitate the delivery of evidence-based medicine on a population-wide basis with a goal of helping each individual in that population achieve optimal health. Disease Management Organizations (DMOs) and other healthcare organizations with substantial resources and access to large patient populations have built the technology platforms and developed the processes and specially trained staff necessary to achieve this goal. And Disease Management supports the Chronic Care Model without imposing financing or access restrictions like capitation and by providing the scalability necessary to handle millions of beneficiaries with chronic conditions.

In fact, DMOs create systems to ensure that the guidelines developed and proven over many years of research by academic and clinical institutions get implemented and that the patients are following the treatment plans prescribed by their physicians.

Disease management programs work by:

- Analyzing, on an ongoing basis, all available data (self-reported, claims, administrative, clinical, encounter) to create a profile of the beneficiary that identifies how severe their illness is and how wide the gaps in the standard of care
- Contacting beneficiaries proactively to gain a better understanding of their psychosocial profile and their willingness to participate and to engage them in an intervention appropriate to their level of severity
- Educating beneficiaries and their family members on self-care skills and providing support to help them adhere to the treatment plan prescribed by their physician and make necessary lifestyle changes
- Monitoring changes in vital signs and symptoms that are indicative of changes in clinical status
- Notifying the beneficiary's personal physician of relevant changes and gaps in the standard of care
- Measuring and reporting on improvements in clinical, financial, and satisfaction outcomes on an ongoing basis

The care gap is particularly acute among our nation's seniors who have high rates of chronic disease and, in the Traditional fee for service Medicare program, there are neither programs nor financing for care coordination on a large scale. Medicare beneficiaries with five or more chronic conditions represent 20 percent of the Medicare population but 66 percent of program spending.[2] They utilize healthcare services at a very high rate and, in the Traditional fee for service Medicare program, have a very fragmented healthcare experience. On average, they:

- Fill 49 prescriptions per year;
- Have 37 physician office visits per year;
- Visit 14 different (unique) providers each year; and
- Stay 7 days in the hospital.

Several approaches have been suggested to fixing this problem in Medicare including:

- Introducing capitation or a gatekeeper structure into the fee for service program
- Increasing reimbursement to physicians who provide care to patients with chronic conditions
- Expanding the benefit structure by adding a variety of chronic care components such as home health visits, prescription drugs, and virtual (email or telephonic) office visits

[2] Berenson & Horvath, "The Clinical Characteristics of Medicare Beneficiaries, March 2002.

While all of these suggestions have merit, the challenge is that these are all incremental changes and do not address the fundamental problems with chronic care that Disease Management can.

- The impact of any one of these changes can't be measured or controlled—which components are truly creating value? How can CMS make sure that services being rendered are truly appropriate to the management of chronic disease? How will the overall cost savings to the trust fund be measured? Population based disease management programs incorporate all of the components required to improve chronic care and are measurable at the population level.
- It is premature to change the physician payment structure without the platform to measure quality and outcomes. Arguments to pay doctors more are about the increased amount of time and staffing resources necessary to care for chronically ill patients. Disease Management programs do nothing to reduce the number of office visits (and, as a result, do not compromise physician reimbursement) but do improve the efficiency of office visits and provide information and support to patients, thereby improving the cost effectiveness of each visit. As a result, the physician's time is more efficiently used and they can treat more patients with less office staff.
- Taking a piecemeal approach to chronic care management would significantly increase CMS's oversight requirements and administrative cost—determining appropriate reimbursement levels, defining eligible services, increasing the number of transactions (claims), etc. With population based Disease Management programs, CMS would need to work with fewer contractors and wouldn't need to change the basic structure of Traditional Medicare.
- These changes are primarily provider-centric and do nothing to reach out to and engage beneficiaries with chronic disease. However, because people with chronic disease are providing their own monitoring and treatment 24 hours a day, they need support and tools to enhance their self-management skills. Population-based Disease Management programs provide this outreach and support.
- Capitation and gatekeeper models limit access to care and eliminate the element of choice fundamental to the Traditional Medicare program. Chronically ill patients generally need to see multiple physicians. The problem isn't one of overutilization, it's how to avoid preventable utilization. Disease Management programs often increase access to primary care and specialist physicians, reduce avoidable hospitalizations and emergency room visits, and operate as effectively in fee for service environments as they do in managed care.

Disease Management programs have been available for several years to Medicare beneficiaries in M+C programs and employer retiree health benefit programs with documented improvements in clinical quality and reduced costs and, as a result, improved quality of life and satisfaction for patients and their physicians.

In spite of being the largest insurance company in the world, however, the Medicare program has lagged the commercial marketplace. This is not for lack of trying. In the past several years, CMS and the legislature have been experimenting with disease management through a variety of small demonstration projects.

Fortunately, the Medicare Modernization Act has now created a framework for transforming chronic care in America. Several sections are devoted to improving care for chronically ill beneficiaries:

- Requirement to coordinate Medication Therapy Management Programs (Section 1860D–4) with DM
- Consumer-directed Chronic Care Demos (Section 648)
- Care Management Pay for Performance Demos (Section 649)
- Requirement for Medicare Advantage (M+C) Plans to have DM (Section 722)
- Increases in payments to Medicare Advantage Plans—such payments to be passed along to beneficiaries—can be used to fund DM programs
- Benefit changes
  - Coverage of Rx
  - Coverage of preventive physical exams
  - Coverage of diabetes screening tests
  - Coverage of cardiovascular screening tests

Most important, however, Section 721 will make large scale, population based Disease Management available to beneficiaries in traditional Medicare. It will for the first time ever provide:

- A single point of contact for beneficiaries to reduce fragmentation
- Education for beneficiaries and caregivers to help manage their self-care

- Technological support and education for physicians and other providers to help them better manage clinical information about the beneficiary
- Biometric monitoring technologies and processes to enhance exchange and timely response to clinical information
- Information to beneficiaries about hospice, end of life, and palliative care

This approach represents real innovation and an opportunity for Congress and CMS to support delivery system change, outreach to chronically ill beneficiaries, and real, measurable reductions in healthcare cost trend and improvements in the quality of life for beneficiaries, their family members, and their physicians. Rather than taking an incremental approach, this bill has jump started the fundamental and necessary change to deal with the chronic care crisis in America.

- It takes a holistic approach to helping beneficiaries deal with their chronic conditions—ensuring that CCIOs focus not just on the primary condition to be managed but also on co-morbidities (other chronic conditions that exist simultaneously in the same person) and that efforts are made to enhance education, access to care, and physician/patient communication
- It is patient/beneficiary centric rather than provider centric and will provide support for beneficiaries that busy physicians cannot afford to provide
- It anticipates the use of proven models of disease management and chronic care improvement that can handle large populations and will be scalable after the initial evaluation phase
- It will result in improved efficiency and increased time for physicians because it addresses many of the problems that chronically ill patients create for physician practices
- It will result in the opportunity to provide enhanced quality of care and quality of life for millions of Medicare beneficiaries without increasing costs to the Trust Fund. In fact, it will result in a guaranteed reduction in costs to the Trust Fund and where else in Medicare have we seen that requirement?
- In addition to resulting in cost savings, it will require clinical quality improvement and enhancement of patient and physician satisfaction
- It will provide incontrovertible proof of the benefits of disease management because of its use of a randomized control methodology and a third party evaluator
- It recognizes the critical importance of Information Technology and data analysis in large scale chronic care improvement efforts
- It has the opportunity to provide measurable, large scale savings because it is population-based (meaning that it holds CCIOs accountable for engaging and then improving quality and reducing costs for all people in the population and it initially targets the conditions (CHF, Diabetes, and COPD) that will yield the greatest immediate savings for the Trust Fund
- It provides an opportunity for all stakeholders to benefit—no one is cut out:
  - Primary care physicians and specialists
  - Home health agencies
  - Community organizations
  - Health insurance carriers
  - Disease Management Organizations
  - Technology companies
  - Beneficiaries
  - Taxpayers (through a more efficient and effective use of the Medicare Trust Fund)

At LifeMasters, we have two recent examples of programs like this that have generated significant results in relevant populations—retirees in a PPO and fee for service Medicaid beneficiaries.

We provided a Disease Management program to the Ohio State Teachers Retirement System whose members received their healthcare through a PPO. We saved the system $8.6 million in total healthcare costs in one year on a 6,000 member subset of their population with CHF, COPD, CAD, and Diabetes. This represented a 6.9% net reduction in total healthcare costs for a 3.5 to 1 return on investment. These savings were generated through an 18% reduction in hospitalizations and resulted in a greater than 90% rate of high satisfaction with the program.

We also provided a Disease Management program to fee for service Medicaid beneficiaries in the state of Florida. Over a two year period we saved the state of Florida approximately $12.6 million on an average population of 3,500 fee for service Medicaid beneficiaries with CHF and comorbidities of COPD, Diabetes, CAD, and mental illness. This represented a 5.6% net reduction in total healthcare costs for a 1.5 to 1 return on investment. These savings were generated through a 38%

reduction in hospital days. The group also experienced significant increases in evidence based care including a 32% increase in patients taking ACE inhibitor/angiotensin receptor blocker therapy and a 77% increase in cholesterol screenings. In addition, there were significant lifestyle changes including an average of 5 pound weight loss across the entire population and 25% of participants quitting smoking.

In another example, American Healthways has provided disease management for one of the nation's remaining Medicare cost-plus plans with its diabetes population since July 1, 2000. It has done the same for this plan's Medicare cost-plus members with cardiac disease since November 1, 2001. In the first two years, the net savings of the diabetes program was $12.9 million, with $5.1 million savings in year one and $7.8 million savings in year two. Net savings in the first year of the cardiac program was $20.2 million. The rates of savings are consistent with American Healthways results in other populations and geographic locations.

These kinds of outcomes have been repeatedly shown in Medicaid, Medicare+Choice, and commercial populations across the country. Extrapolating these savings to the Traditional Medicare population, Disease Management or chronic care improvement programs could save billions of dollars while concurrently enhancing the quality of life for millions of beneficiaries and their family members.

There are many models possible under MMA and CMS has encouraged consortia to apply for pilot projects. I can attest that my company and several members organizations of DMAA are actively working toward building solutions that are collaborative in nature.

Here's how some of these consortia might work:

- A multispecialty physician group or integrated delivery system with sophisticated information technology including electronic medical records and claims analysis capabilities, established disease management programs, and a high risk case management program contracts directly with CMS. The physician group subcontracts with a call center company to perform the outreach and enrollment functions to get the intervention group engaged but performs all of the chronic care improvement functions on its own and holds all of the financial risk. The revenue flows to the physician group or IDN which uses the money to fund its services and subcontract and also to establish differential payment systems (pay for performance) for their physicians based on the outcomes and their willingness and effectiveness in participating.
- A health plan subcontracts with a DMO. The DMO provides the outreach, educational, support, and monitoring services. The health plan provides high risk case management and home health services. The revenue flows to the healthplan which uses the money to pay the DMO for its services and also to cover its high risk case management costs, home health costs, and a risk premium to hold the bulk of the financial risk. The DMO retains a portion of the financial risk to ensure that incentives are aligned.
- A DMO contracts directly with CMS for a program. It provides all of the standard disease management services and subcontracts with a home health agency, a biometric monitoring company, and a high risk case management company if needed. At the local level, the DMO also identifies and develops relationships with community agencies that provide social services to seniors. The revenue flows to the DMO which uses it to cover its own costs and to pay the subcontractors and perhaps even provide funding for the community agencies. The financial risk is carried by the DMO which may allocate some of this risk to its partners depending on what services they provide.
- A pharmacy benefit management company (PBM) that is planning on being a Prescription Drug Provider (PDP) under the new drug benefit partners with a physician group practice with an established disease management program or a DMO. The PBM begins offering a modified drug benefit prior to the 2006 drug benefit start date and includes a Medication Therapy Management (MTM) program. The DMO provides the DM services. The PBM and DMO integrate their data systems and builds interfaces between the DM and MTM programs.

In closing, I'd like to express my sincere thanks on behalf of the entire disease management community to you, Mrs. Johnson, and the entire Committee, Chairman Thomas, Secretary Thompson, and the leadership at CMS for your leadership in making these important services available to the millions of seniors with chronic conditions in America who need the support and programs to help them lead a better quality of life.

As you may know, DMAA has submitted an extensive set of comments and recommendations to CMS in response to the RFP recently issued for Phase 1 of the Chronic Care Improvement program. In addition to that submission, I'd also like to

make a few recommendations that I hope might help improve the effectiveness of this valuable program:

- That you continue to support CMS with the resources they will need to build the infrastructure necessary to administer and monitor this program
- That you consider the implementation of disease management programs whenever you take on Medicaid reform
- That CMS consider accreditation by one of the major accrediting bodies—or at least a set of minimum criteria—as a threshold for contracting in order to ensure consistency and a standard level of quality
- That CMS consider incentivizing chronic care improvement organizations to devote resources over and above those necessary to achieve the minimum net savings requirement by allowing them to receive a share of savings over and above the 5% minimum guaranteed financial savings
- That CMS consider implementing all of the pilot programs simultaneously rather than staging implementation over an extended period of time in order to ensure that results can be measured equitably and consistently
- That you and CMS be open to expanding the program earlier that the currently specified two years from inception when the results begin to show the expected cost savings and quality improvements
- That CMS ensures that models selected provide a win-win for all stakeholders in the chronic care community
- Yet at same time, ensure that models selected have proven outcomes and reflect models that can be easily scaled for Phase 2. While we applaud the concept of experimentation, we want to make sure that this program is successful in reducing costs and improving the quality of life for the millions of beneficiaries with chronic disease and their families

Thank you again for the opportunity to comment on the Chronic Care Improvement program and I would be happy to try and answer any questions you might have.

Chairman JOHNSON. Thank you very much, Ms. Selecky. Dr. Wright.

STATEMENT OF JANET S. WRIGHT, MEDICAL DIRECTOR OF CARDIOLOGY, ENLOE MEDICAL CENTER, CHICO, CALIFORNIA

Dr. WRIGHT. Good afternoon. I also appreciate this opportunity to come before you. As I mentioned in my written comments, I couldn't presume to represent all the opinions of cardiologists in the country, but I do come here on behalf of my patients and what I think—on behalf of the hope that this is a breakthrough to improve medical care. I decided rather than read to you excerpts from my written comments that I would tell you a story that I hope illustrates my personal experience with the transformation of medical care.

Bill Cosby started an album, "A long time ago, I started out as a child." Well, I started out as a medical child. My father practiced family medicine in a small town in Arkansas for almost 50 years. He took care of a chunk of people in northeast Arkansas. For many of those years, my mother was his nurse. At night, on weekends, summer and Christmas vacations, I ran the front desk. I took cash and I recorded dutifully—on those folks who came under a farm account, I recorded their care in a ledger. The three of us were essentially the health care delivery system.

I learned a lot of things from my parents and I learned, I think, how to do medicine. My father was available 24/7. He did not have an unlisted number. Everyone knew my dad's number. I learned to answer the phone, "Dr. Wright's residence." I learned early on to hear the anxiety that is in a sick person's voice.

We used to joke that a light went on in the water tower when we sat down to dinner, because that is when the phone started to ring. I remember that my father felt privileged to be a physician. He drew tremendous satisfaction from his job. I think the reason he did is that he worked hard, he prepared well, but he also felt he was doing a good job for his patients. I also remember him escaping occasionally the 30 miles or so to Memphis to spend a night in a hotel. He did what I called the death sleep where we often wondered whether he was alive, but he used it as a recovery.

That deep satisfaction made a great impact on me and, in fact, it bent my career early toward medicine. I could have done nothing else. So, I will tell you about the 48 hours that I spent before I came here. I was on call for my group of seven. As I said, I am a cardiologist so that limits my scope already. I think I had 56 patient encounters in that 48 hours. I took the numbers down because I thought you might be interested.

Out of those 56 encounters, 27 of those people were over the age of 80. As you know, we make problem lists and no patient had a problem list shorter than three; that was the 39-year-old. Everyone else had problems listing up to 12 or 15.

I was usually one of three specialists on each of those person's case. If you think that the lab sheet we look at, about 3 different sets of lab sheets and 3 times 58 comes out to be 168 or something, there were a lot of lab tests to go over.

My practice is different than my father's practice, but the requirement for satisfaction is just as great; and although a different reimbursement might give me some satisfaction, taking better care of my patients will give me the best satisfaction. I think that is what pulls my interest into disease management.

From what I have read and what I have observed, their approach, looking at large numbers of people with similar medical problems who still need individual care and who need care continuously rather than episodically, makes a lot of sense; and I think physicians need the benefit of their expertise.

I think physicians, as you mentioned, Representative Stark, are beleaguered. In addition to the five sources of information telling me how to practice, I also have the entire Internet source telling me how to practice, but I do need some assistance. I think there is hope in this program to learn from the initial experiments and then apply those in wider spectrums, not just to all my beneficiaries, but in different settings of practice; not just in large groups, as you said, Chairman Johnson, but in the smaller, individual practices. I appreciate all of your efforts on our behalf.

[The prepared statement of Dr. Wright follows:]

Statement of Janet S. Wright, M.D., Medical Director of Cardiology, Enloe Medical Center, Chico, California

Chairman Johnson and members of the subcommittee:

I am here today as a practicing cardiologist and a Fellow of the American College of Cardiology, (ACC) an organization whose mission is to advocate for quality cardiovascular care-through education, research promotion, development and application of standards and guidelines-and to influence health care policy. My comments reflect the policy position of the College, although I could not presume to represent the diverse opinions of the over 30,000 members of the ACC. I do however, represent the interests of my patients and on their behalf, I express my gratitude for the efforts you make on a daily basis to improve health care in America. I believe that your

contributions will initiate an historic improvement in the quality of health care for Medicare beneficiaries.

Any policy maker, health care professional or sick person in America knows that our health care system is broken. Our striking success in combating life-threatening illnesses has extended the lives of millions of Americans, and in that victory, converted acute events into chronic conditions. Our older citizens suffer multiple diseases, visit an average of seven doctors a year, and take more than twice that many medications each day. These patients need near-constant oversight and continuous care coordination to stabilize their conditions and to avoid the episodic, usually urgent and costly rescue from a preventable deterioration.

As seniors' complex medical conditions multiply, the physician workforce is shrinking due to unmet needs for job satisfaction, adequate reimbursement, and liability protection, among other factors. Quality medical care takes time and resources to deliver and good doctors are struggling these days to care for the burgeoning chronic disease population. The therapeutic alchemy of the patient-physician relationship disintegrates under the pressures of today's fragmented care interaction. When the personal connection breaks down between patient and doctor, so does adherence to advice, trust, satisfaction, and inevitably, the clinical outcome. To deliver excellent care, physicians need additional resources to provide patient and family education, to track practice adherence to established guidelines, and to supply our statistics to a variety of "measurers" in the health care arena. To practice 21st century medicine, practitioners must have current, complete, and accurate data. Those data, and the resources for gathering them, are absent in most medical practices today.

Advances in science, funded robustly by this Congress, have been translated into evidence—or guideline-based medicine, setting the standards of care and shaping medical decision-making. Yet few doctors can afford the information technology or human resources to bring these recommendations to the point of care delivery, much less to record, track, and report their performance, an increasingly common requirement in the medical marketplace. Despite best efforts of well-trained and dedicated physicians, our own measures of quality have demonstrated dispiriting gaps in care. Health care has metamorphosed; health care delivery systems have not.

Although I do not know the solutions to our complex health care crisis, I can list the basic characteristics of those solutions. **Collaboration** is critical as the problems are clearly insurmountable by any single organization or entity. Improvements will be **incremental** or staged because the distance we must travel from our present state to a significantly better one is staggering. **Evidence or guideline-based** medicine is the accepted standard, and a steady **focus on quality,** with all the attendant difficulties, will help guide us to a better system of care. The solution must be **comprehensive,** in the sense that quality care is to be delivered in all settings, for all conditions. Finally, and most importantly, the new system will be marked by **enhanced communication** on the macro level by adaptable IT and appropriate infrastructure, and on a personal level by a resuscitated patient-physician relationship.

The approach known formally as disease management has grown exponentially in the current chaos because it provides among other things, vital systematic links among participants in the health care system. Emphasis on populations, self-care instruction, and continuous cross-talk between patients and the care team mark a few of the unique features of the disease management approach that are missing in the traditional care model. Disease management harnesses information technology and other important tools to assist with application of evidence-based medicine, data collection and analysis, patient and physician adherence, and performance enhancement. Disease management brings constructive additions to current health practices and holds promise for improvements in care delivery.

As an example of highly effective disease management, I call your attention to a mature and profoundly valuable program which has provided education in self-management and health preservation, linked patients and doctors through frequent progress reports, and not just satisfied, but indeed, life-changed its participants. That program is one of the original disease management approaches known as Cardiac Rehabilitation. The design has from its inception been multidisciplinary, bringing together cardiac nurses, exercise physiologists, dieticians, and cardiologists with expertise in disease prevention and health promotion. These sophisticated programs begin with detailed intake interviews, identifying not only the medical conditions which require monitoring and management, but also the social and psychological hurdles to achieving and maintaining good health. The structured weekly sessions provide the continuous and repetitive feedback proven to effect changes in behavior. The care team members support these gradual, key behavioral shifts, become trusted sources of information, and most importantly, serve as community-extended

radar, detecting early signs of decompensation, medication errors or poor adherence, and new or recurrent disease states.

Patients undergoing cardiac rehabilitation "graduate" armed with knowledge of their disease process, their prognosis, and their limitations; the latter most certainly reduced by the personalized protocol of exercise, nutritional counseling, stress-reduction training, and medical supervision. In these days of "drive-by" open heart surgery and two-day admissions for heart attacks, the educational process is so critical for the restoration of physical and mental health and improved functional status takes place in one and only one place: Cardiac Rehabilitation. Even with the fiscally constrained reach of cardiac rehabilitation programs, the disease management principles have succeeded in improving the outcomes and outlook for patients with cardiac disease.

The Voluntary Chronic Care Improvement Programs will incorporate many features present in the CR/DM model, features which are fundamental to solving our health care crisis. This unique design calls for collaboration among the system experts (DM), the medical pros (physicians and health care team), and the payers in a mutually rewarding arrangement for the benefit of patients with congestive heart failure, complex diabetes, and chronic obstructive pulmonary disease. The successful models/components will be identified in a three-year process and made available to the appropriate Medicare population in a staged fashion. Outcome measures of quality and satisfaction will be selected in advance, monitored, and reported, highlighting the use of information technology and reinforcing the practice of guideline-based medicine.

Even though there are specific targeted diseases in the Phase I programs, the approach is most appropriately comprehensive in the attention given to co-morbid conditions and overall health status. This is both complicating for the program administrators and absolutely necessary for the applicability of these approaches to real-life medical care of aged and disabled Americans. Cost data will be important, but not sole determinants of program success. Although typically unprofitable for hospitals, cardiac rehabilitation programs achieve striking gains in quality of life, patient satisfaction, and clinical outcomes. Phase I programs that predominantly emphasize well-established clinical outcomes are in the patients' and ultimately, the country's best interest. In fact, the very foundation of a disease management strategy is that early and frequent intervention (whether education, medication adjustment, further evaluation, and/or alteration in treatments) improves the patient's ability to function at the highest level possible. I strongly encourage selection of programs that focus on quality improvement, as those are most likely to result in concomitant enhancements in beneficiary and provider satisfaction. Finally, I trust that the programs selected for Phase I will recognize the therapeutic value of a healthy patient-physician relationship and will support fluid communication among members of the care team, family members, and caregivers.

In Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Congress has broken new ground in health care delivery design. Many aspects of the MMA are revolutionary in the transformation of health care in the United States. New partnerships will be formed, innovative approaches will be tested, and the underlying audacious concept is that quality medical care will lead to better financial, satisfaction, and clinical outcomes.

That said, I believe that the greatest achievements of this legislation will be realized in an evolutionary way. Section 721 sets in motion a new direction in health care which will find expression in ways we cannot anticipate. We will learn from the experience of Phase I, and future innovators and disseminators will adapt the processes as populations and medical conditions mandate. I expect to discover through the Phase I project, the techniques and processes that work and those that need further modification or perhaps application in a different subset of patients. Learning where and how and in whom to apply these principles of care will be an invaluable lesson. I anticipate that practices, health plans, and other care delivery systems which are not part of the Phase I projects will follow the progress reports closely and begin to implement the winning strategies. The goal is to improve the quality of care for all, to close the gaps that still exist, and to do so in a cost effective manner which will enable us to provide care to all in need. It is my hope that as much meticulous care and concern go into these future designs as was invested in the crafting of this legislation and in its implementation.

I encourage physicians to investigate the Chronic Care Improvement Programs, to consider the potential benefits to their patients and their practices, and to participate however possible so that the ultimate delivery model reflects what we know to be true: compassionate individualized care is effective, essential, and rewarding. We will always treat one human being at a time and, in that moment, serve the larger population well. The opportunity now presents to combine this best practice

of the healing arts with a high tech, population-based approach, a challenge which calls for the integrity and commitment of the brightest minds in health policy, system design, and medicine.

In closing, I share a physician's wish list for the future perfect state of medical care. Many of these wishes could come true in the Phase I and II programs and they are essential components of a fit and functional health care system.

1. I want to be on the design team for the process of care. (Physician involvement)
2. I want to know my "score," how it is calculated, and to whom it is reported (Quality/performance measurement)
3. I want my patients to have ready access to a team of experts in my practice and community who can extend health care beyond our office visit. (Team care, primary and secondary prevention)
4. I want current, accurate, complete data available when I need it so that I can incorporate it into my practice. (Information technology)
5. I want my patients to have validated, self-care advice when they need and so they can use it. (Patient education, prevention, information technology)
6. I must have the ability to afford to deliver this care. (Adequate reimbursement for a chronic care management system)

I deeply appreciate the efforts of this subcommittee in improving our health care system. Your dedication and commitment challenge all participants in health care to contribute our best to achieve creative and cooperative solutions.

Chairman JOHNSON. Thank you very much, Dr. Wright. Dr. Bufalino.

STATEMENT OF VINCE BUFALINO, M.D., MEMBER, EXPERT PANEL ON DISEASE MANAGEMENT, AMERICAN HEART ASSOCIATION, NAPERVILLE, ILLINOIS

Dr. BUFALINO. Thank you. Good afternoon, Madam Chairman, Representative Stark, Representative Crane. I thank you for the opportunity to testify on this important initiative. My name is Vince Bufalino. I am a practicing cardiologist for 22 years and the President/CEO of Midwest Heart Specialists, a 55-physician practice in suburban Chicago.

I have been an active volunteer for the AHA over the last 20 years and the incoming Chairman of the Advocacy Coordinating Committee nationally, and also serve as the Chairman of the Emergency Cardiac Care Committee where we direct Cardiopulmonary resuscitation and Advanced Cardiac Life Support programs for the United States. Currently, I am the president of the Midwest Region, of the seven States, and have been named to the board of directors. Finally, and why I am here is, I am a member of the AHA's Expert Panel on Disease Management.

I am speaking today on behalf of the AHA's 22.5 million volunteers. As the largest voluntary health organization, the AHA's mission is to reduce cardiovascular disease and stroke by 25 percent by the end of this decade. Our organization is unique. Our volunteers are patients, physicians, nurses, and other stakeholders, all dedicated to fighting heart disease and stroke, our Nation's number one and number three killers.

The AHA believes that chronic care management programs, if properly structured and carefully implemented, may help transition the Medicare Program into a more responsive and comprehensive health care program for America's seniors.

We are encouraged that the voluntary CCIP appears to be an important step in this regard. We applaud your leadership, Madam

Chairman, in ensuring that this issue was addressed in the MMA. We look forward to working with you, this Committee, and CMS to ensure that the CCIP fulfills its considerable promise to demonstrate improvements in patient outcomes and quality of life.

We believe CMS has done an admirable job in developing the RFP. Much of what will ultimately matter most, however, cannot be explicitly detailed in an RFP. True success will depend on the extent to which this program recognizes and promotes practices to provide value to our patients. By this, I am referring to improved patient outcomes, the translation of evidence-based research into practice, the institution of measures to promote primary and secondary disease prevention, and effective beneficiary outreach so the beneficiaries can understand the true benefits of this program. If, however, the program becomes overly focused on reducing expenditures, we are concerned that much of the potential value to the patient may not be realized.

I would like to devote my comments today to a series of recommendations focused on these issues that we believe address the improved patient outcomes for Medicare beneficiaries. After conducting extensive research, the AHA's Expert Panel has established a set of principles on disease management and chronic care management. We believe these principles should be applied to chronic care management programs in both the public and private sectors and consistently across disease states and patient populations.

Although the number of existing disease management programs and chronic care programs seek to balance cost containment with quality, quality and improved patient outcomes must always be the priority. The AHA recommends the following guiding principles for the implementation of the CCIP.

Number one, the main goal of CCIPs should be to improve the quality of care and patient outcomes. The core principle underlying all of our recommendations is ensuring treatment and practices that improve outcomes. We appreciate the fact that this principle was the motivation for the inclusion of the CCIP in the MMA. Our challenge, however, is to implement this program in a way that meets the objective.

Number two, evidence-based guidelines should form the foundation for all CCIPs. Efforts to manage beneficiaries with chronic conditions should incorporate the use of guidelines such as those developed by the AHA and other organizations in the medical community that provide clear direction as to how to reduce the risk of these chronic conditions and to ensure the beneficiaries received optimal care.

Number three, performance measures should be designed to improve quality of care in clinical outcomes. Scientifically based quality indicators should be the key measurement upon which the success of the CCIP is evaluated. Careful attention should be given to the appropriate translation of these scientifically based guidelines into chronic care practices.

Number four, to ensure the optimal patient outcomes, the CCIP must address the complexities in medical co-morbidities. According to recent research, 78 percent of the medical beneficiaries in Medicare have at least one chronic illness. Almost 32 percent have four

or more. Chronic care improvement must include the management strategies for these complex interactions.

Number five, scientifically based evaluations should be a critical component of all of these programs. Ongoing evaluation efforts should examine the extent to which the chronic care management efforts have produced better quality of care and improved clinical conditions for our beneficiaries.

Number six, the chronic care management program should exist within an integrated and comprehensive system of care in which the patient-physician relationship is central. Chronic care management services should not substitute a patient-provider relationship, particularly the patient-physician relationship, that is critical to the delivery of care. Instead, chronic care management programs should be one of several strategies to support and enhance the patient-provider relationship.

A significant challenge exists for the enrollment of these beneficiaries in the CCIP. Successful enrollment will be closely linked to beneficiary education and outreach. Outreach efforts should include clear and easily understood information for beneficiaries that helps them understand the impact of this program. Beneficiaries should know that this new program will not force them to give up their doctor or reduce their current benefits. Instead, this pilot program should help them coordinate what is oftentimes a fragmented health care system through which the beneficiaries receive their care.

In addition, beneficiary participation will be influenced by its impact on the patient-physician relationship. Individuals will not be receptive to a program that threatens their ability to be treated by their physician of choice or otherwise intrudes on this relationship. We urge CMS to reject proposals that attempt to supplant the care provided by the patient's provider.

A beneficiary willing to participate in the CCIP is also dependent on his or her understanding of this program, its benefits, its processes, and its objectives. The CMS must ensure that chronic care improvement organizations engage in substantial education efforts to inform the beneficiaries how the CCIP will improve quality of care, prevent future adverse events, and improve outcomes. Patients and their physicians must be convinced that the program will utilize the best science to aid in determining the most effective treatment course.

Finally, it is important to recognize that each geographic area chosen for this program will have its own unique cultural and linguistic characteristics. In order for any beneficiary communication effort to be effective, it must consider these factors and develop outreach activities in a culturally significant manner. The AHA appreciates the opportunity to testify before the Committee on this important issue, and we look forward to working with you and CMS on this important initiative. Thank you.

[The prepared statement of Dr. Bufalino follows:]

Statement of Vince Bufalino, M.D., Member, Disease Management Expert Panel, American Heart Association, Naperville, Illinois

Introduction

Good morning, Madame Chairperson and members of this Committee. Thank you for the opportunity to testify on behalf of the American Heart Association before your committee on this important initiative.

My name is Vince Bufalino. I am the President/CEO of Midwest Heart Specialists, a 55 physician Cardiology practice in the Chicagoland area with fifteen offices located in the western and northern suburbs. As chairman of the Midwest Heart Foundation, a non-profit research arm of Midwest Heart Specialists, I oversee approximately 30 clinical research trials.

I have been an active volunteer for the American Heart Association for the past 20 years. I am the incoming chair of Advocacy Coordinating Committee nationally and serve as national chairman of the Emergency Cardiac Care Committee with responsibility of directing the CPR and Advanced Cardiac Life Support Programs for the United States.

I am also currently president of the American Heart Association's Greater Midwest Affiliate and have recently been named to the AHA Board of Directors and Administrative Cabinet, both at the national level. Finally, I am an active member of the AHA's Expert Panel on Disease Management.

I am speaking today on behalf of the American Heart Association and its 22.5 million volunteers and supporters. As the largest voluntary health organization, the American Heart Association's mission is to reduce cardiovascular disease and stroke by 25% by 2010. Our organization is unique. Our volunteers includes patients, physicians, nurses and other stakeholders dedicated to fighting cardiovascular disease and stroke, our nations #1 and #3 killers respectively.

The American Heart Association believes that chronic care management programs, if properly structured and carefully implemented, may help transition the Medicare program into a more responsive and comprehensive health care program for America's seniors.

We are encouraged that the Voluntary Chronic Care Improvement Program appears to be an important step forward in this regard. We applaud your leadership, Madame Chairperson, in ensuring that this issue was addressed in the Medicare Modernization Act. We look forward to working with you, this committee, and the Centers for Medicare and Medicaid Services (CMS) to ensure that the Voluntary Chronic Care Improvement Program fulfills its considerable promise to demonstrate improvement in patient outcomes and quality of life.

We believe CMS has done an admirable job in developing the request for proposals for this program. Much of what will ultimately matter most, however, cannot be explicitly detailed in an RFP. True success will depend on the extent to which the program recognizes and promotes practices that provide value to the patient. By this, I am referring to improved patient outcomes, the translation of evidence-based research into practice, the institution of measures to promote primary and secondary disease prevention, and effective beneficiary outreach so that beneficiaries can understand the benefits of this program. If, however, the program becomes overly focused on reducing expenditures, we are concerned that much of the potential value to the patient will not be realized.

American Heart Association's Principles for Chronic Care Improvement Programs

I would like to devote my comments today to a series of recommendations focused on issues that we believe must be addressed to ensure improved patient outcomes for Medicare beneficiaries in the implementation of the Chronic Care Improvement Program. After conducting extensive research, the American Heart Association Expert Panel on Disease Management established a set of principles on disease management and chronic care management. We believe that these principles should be applied to chronic care management programs in both the public and private sectors and consistently across disease states and patient populations.

Although a number of existing disease management programs and chronic care management programs seek to balance cost containment and quality, quality and improved patient outcomes must always be the priority.

The American Heart Association recommends the following guiding principles for the implementation of the chronic care improvement program to ensure improved patient outcomes for Medicare beneficiaries:

1. **The main goal of chronic care management should be to improve the quality of care and patient outcomes.**

Evaluation of chronic care management programs should be based on more than just a reduction in health care expenditures. The emphasis should be on the "value" of chronic care management (i.e., the extent to which chronic care management efforts result in better quality for a given investment rather than on cost savings alone). Improvements in quality of care and patient outcomes should be the primary indicator of successful chronic care management. The use of performance standards in assessing quality of care and outcomes is critical in evaluating success.

2. **Scientifically derived, evidence-based, consensus-driven peer reviewed guidelines should be the basis of all chronic care management programs.**

Chronic care management strategies should be derived when available from scientifically-based guidelines such as those written by the American Heart Association/American Stroke Association and groups such as the American College of Cardiology and the American Academy of Neurology. These guidelines represent consensus in the cardiovascular disease and stroke communities regarding appropriate treatment and management of patients with cardiovascular disease and stroke. Careful attention must be given to the appropriate translation of these scientifically based guidelines into chronic care management practices.

3. **Chronic care management programs should include consensus-driven performance measures.**

Improved quality of care and outcomes for patients with cardiovascular disease and stroke should be the pivotal measurement upon which the success of a chronic care management program is evaluated. To measure improved quality of care and outcomes, consensus-based performance measures should be used to evaluate a chronic care management program's effectiveness. Performance measures used in evaluating chronic care management programs should be those measures that are developed by a broad consensus-driven process such as the National Quality Forum and/or others. Ideally, these performance measures should be evidence-based.

4. **To ensure optimal patient outcomes, chronic care management programs should address the complexities of medical co-morbidities.**

Many chronic care management programs are designed to treat single disease states. A significant population of patients with chronic disease suffers from multiple co-morbidities. Some of the greatest challenges in caring for these patients involve the complex interactions of these co-morbidities. Chronic care management programs and guideline committees should develop algorithms and management strategies to fully address patients with co-morbidities.

5. **All chronic care management efforts must include ongoing and scientifically based evaluations, including clinical outcomes.**

Chronic care management programs have not traditionally undergone rigorous scientific evaluation regarding their impact on patient outcomes. The true measure of any health intervention is whether patients are better off having received the service or care provided. This determination requires a meaningful examination of clinical outcomes. Frequent scientifically-based evaluations should be included as a critical component of any chronic care management program, and these evaluations should allow for continued improvement in the program to maximize benefit.

6. **Chronic care management programs should increase adherence to treatment plans based on best available evidence.**

An important focus of chronic care management should be to influence the behavior of providers, patients and other caregivers to better understand and adhere to treatment plans that will help improve patient outcomes. The targets of such efforts may include a broad community of caregivers, e.g., physicians, nurse practitioners, family members and community-based organizations. To be meaningful, it is essential that such treatment plans be derived from the best available clinical and scientific evidence. The evidence and resulting treatment plans should be revisited periodically to reflect evolving standards and scientific knowledge.

7. **Chronic care management programs should be developed to address members of the under-served or vulnerable populations.**

Currently, most chronic management programs arise from employer-based, private health plans. Although a number of states have begun using chronic care management approaches within their Medicaid programs, in general, most chronic care management programs serve an employed, insured and healthier population. Chron-

ic care management programs should be developed to incorporate or to specifically address the unique challenges of the under-served and vulnerable populations.

8. **Chronic care management programs should exist within an integrated and comprehensive system of care, in which the patient-provider relationship is central.**

Chronic care management services should not substitute for the patient-provider relationship(s), particularly the physician-patient relationship that is critical to the delivery of effective care. Instead, chronic care management programs should be one of several strategies employed to support and enhance the patient-provider relationship, resulting in an overall improvement in the quality of care and coordination of care delivered to patients with cardiovascular disease and stroke.

9. **Organizations involved in chronic care management should scrupulously address and avoid potential conflicts of interest.**

Organizations that provide chronic care management services should act in the best interest of the patient and avoid conflicts of interest. The primary goal of chronic care management organizations should be to improve patient outcomes. Efforts to achieve secondary goals such as product marketing or product sales, should not adversely affect the primary goal of improving patient outcomes. To the extent any conflict of interest arises that may compromise the primary goal of improving patient outcomes, it should not be pursued.

Beneficiary Outreach and Education Should be Prioritized

A significant challenge exists for enrollment of beneficiaries in the new chronic care improvement program. Successful enrollment will be closely linked to beneficiary education and outreach.

Outreach efforts should include clear and easily understood information for beneficiaries that will help them understand the impact of this new program. Information and outreach to beneficiaries should be provided to help them understand that this program will not replace their relationship with their physician but instead, if done correctly, it will supplement or enhance the patient-physician relationship. Beneficiaries should know that this new program will not force them to give up their doctor or reduce their current benefits in any way. Instead, this pilot program should help coordinate what often times is the fragmented health care system through which beneficiaries receive care.

In addition, beneficiary participation is influenced by its impact on the physician-patient relationship. Individuals will not be receptive to a program that threatens their ability to be treated by their physician of choice or otherwise intrudes upon the physician-patient relationship. In order to succeed, the CCIP must be viewed and implemented as a tool to support and enhance existing provider-patient relationships. We urge CMS to reject proposals that attempt to supplant the care provided by a patient's provider of choice.

A beneficiary's willingness to participate in the CCIP also is dependent upon his or her understanding of the program—its benefits, processes, and objectives. Thus, beneficiary education and outreach are essential. CMS must ensure that chronic care improvement organizations engage in substantial education efforts to inform beneficiaries about how the CCIP can improve the quality of care, prevent future adverse events, and improve patient outcomes. Patients and their physicians must be convinced that the program will utilize the best scientific research to aid in determining the most effective course of treatment.

Patient communications must facilitate enrollment. Special efforts should be made to emphasize the voluntary nature of this program with beneficiaries. If the enrollment process is perceived as too complex, it may serve as a disincentive to beneficiary participation.

Finally, it is important to recognize that each geographic area chosen for the program will have its own unique cultural and linguistic characteristics. In order for any beneficiary communication effort to be effective, it must consider these factors and develop outreach activities in a culturally sensitive manner.

The American Heart Association appreciates the opportunity to testify before the Committee on Ways & Means Subcommittee on Health on this important issue, and we look forward to working with Congress and CMS on this important initiative.

Chairman JOHNSON. I thank you all for your testimony. I want to clarify. First of all, you have all pointed to important aspects of

how this program must work. Certainly it must work with physicians and not be dictated to physicians. It has to be collaborative at every level and throughout its parts. I do want to point out something about the underlying law that some of you may be aware of, but not all of you.

While these RFPs do require that you demonstrate savings, the underlying law does not. The Secretary retains the authority to roll out to the broad Medicare Program things that improve health quality, the quality of care and patient satisfaction, even if they do not save money. Now, he does not have that authority if they cost money, but he does have that authority if they just improve quality and do not save money.

So, we were very deliberate in how we wrote the law so that saving money would not be one of the criteria that you had to meet in order to roll out an initiative in this area. You have to meet a criterion that enables you to demonstrate there is an improvement in patient quality and patient satisfaction. So, while I was not entirely happy with the 5-percent savings, I think, on these particular ones they are starting out with, that should be able to be met; and there seems to be no disagreement in the provider community that that was able to be met, and certainly the huge response to these RFPs indicates that that does not seem to be a problem.

I did want you to know that that does not hamper the Secretary's authority in the future. I also want to thank you, Dr. Wright, for the story about your father's practice and your practice. That is a very, very important story. It is important that there were three of you in most of these cases.

It is important that the quantity of medical knowledge is exploding at such a rate that it is very hard to keep track. I have had many physicians report to me to have some program that can remind your patient to come back, can make sure they bought the next refill of their prescriptions to keep the process of care moving accurately in a way that it would be very hard for a physician and his staff to do without today's technology and the automatic flags that it can raise.

I also want to mention an experience that we had at the press conference, that the Secretary and I had, announcing the RFPs, because your comment about needing care immediately as opposed to intermittently is really the heart of this change and doctors know it. It is not that they do not know it; it is that we do not know it, and we cannot recognize it in our payment structure. We do not recognize it until something is bad enough, until it triggers a doctor's office visit or hospital visit.

We had very interesting testimony or a comment at the press conference from a well-educated gentleman who was about 80, who was diagnosed with diabetes when he was 48 or 42. He was experienced as a young person in managing diabetes, he was experienced as a retiree in managing diabetes; and about 5 years earlier he had gotten into one of these chronic disease management programs.

What was spectacular about it was that his mental health was so much better. He understood so much more about his disease. He felt so at home about it. He made the statement that, "I always felt sort of selected for this terrible burden, resentful of this terrible burden, angry at this terrible burden of diabetes; and now I under-

stand it is just part of my body. It is the way things function. I can understand it. I know about it. I can manage it. Furthermore, I have an expert friend who is there as close as the telephone to ask any question about it."

Now, when you look at how we are using the Internet and the possibilities for communicating, no doctor can absorb all of those communications and still see the number of patients that it is important for him or her to see. So, if you want to talk about any aspect of that, this continuity of care and this continuousness of care, that is what is unique about chronic disease management, it would be helpful to us or anything else you want to add. Dr. Wright.

Dr. WRIGHT. Thank you. I had the privilege of sitting in on that press conference and that patient's words, what he said exactly was, "I finally got friendly with my diabetes." I thought that was so powerful after having fought it so long as the enemy.

Chairman JOHNSON. It is not that he did not have good coverage. He had terrific coverage. He had retiree coverage. There is a need that incident-based health care cannot meet and we have got to understand that.

Now, there is also a way in which not only does our payment system not reimburse for that, but we are positively hostile to it. The Inspector General will look over your shoulder and say, you did not need to do that; that was not necessary. So, meeting this challenge as to how we restructure the payment system is going to be a big challenge, and I think this variety of pilots will help us. You need to make sure that the doctors in your area, in your specialty, and the doctors in other specialties begin to think about this, and that you work collaborative.

I want to know, if all three of you on these cases sat down and figured this out, what solution would you—would you tell us, what would you tell us to pay for and how would you tell us to pay for it? So, in your spare time if you would raise that.

Dr. WRIGHT. Yes. I have a plane ride back tonight. The frightening thing to me is not so much that 48 hours of call and the fact that there were so many specialists, but my hospital, which is an excellent institution, it has invested in a good computerized system, not a computerized medical record, but at least lab data that pops up and we can download it on a computer and get access to it. So, we are caring for those patients in-house pretty well.

Those patients are discharged from the hospital into those specialists' offices, all of which are spread out over a two-county area, and there is no link between the nephrologist's office and my own except for me. That is where the system really disintegrates, trying to manage chronically ill patients, people who are sick every day of their lives, trying to help manage them episodically. We do it and we wait until they get sick enough to come back into the hospital. That is not a good plan.

Dr. BUFALINO. One other comment to add to that. The congestive heart failure that we are talking about today is surely one of our biggest challenges. These are our sickest patients. So, your comments about the need for continuum are critical.

Although we have episodic care when they are really sick in the hospital, our biggest need is over the time frame when they are at home and needing follow-up. Most of these patients are on 8 to 12

drugs, with a fair number of interactions, obviously. We have had to, in our own practice, extend ourselves by using nurse clinicians in the office setting by being able to connect to them at home, to be able to follow up and do some of the visits, because we cannot meet the need.

So, we are always in need of more effort to be able to connect to this sickest group of patients, and they tend to have the most confusing set of problems altogether. A lot of what you heard today is that four or five illnesses are routine in a lot of the Medicare patients because these things all interact together. They have diabetes, high blood pressure, high cholesterol, bad arteries and a weak heart all together. That is a typical story. So, we are clearly challenged.

Chairman JOHNSON. It is important for all of you and particularly for your group and their nurse practitioners to be able to think through exactly what do those nurse practitioners do. We tried to do that in the disease management section of the bill with enormous help from the disease management professionals. We need to know, what are those practical things that we would include were we to give a reimbursement, so there is as clear a delineation as possible? Because the clearer the regulations are, the less the Inspector General causes problems. Now, I have respect for the Inspector General, but you can micromanage this law so that you do not have much left at all.

So, I do appreciate those comments and I urge you to encourage the physicians to think, if we were to accept a global fee for all of this, what would be the things that we needed to say we would be able to do? Even to look at these requests for proposals, if that were out there just as a reimbursement for you all, rather than a whole system of care, does it include everything that you do? What would be the appropriate payment?

So, we do face a lot of challenges, but we cannot, we cannot continue with the current system we have. That is why passage of this bill called the MMA was crucial, because we were making no progress on what is the most underlying challenge in Medicare and that is to modernize what it is we are paying for and how we are relating to our own providers. So, thank you very much. Mr. Stark.

Mr. STARK. Thank you, Madam Chairman.

I guess CCIP fills the gap for certain people. I guess mostly those who are healthy enough to manage their own care and respond to suggestions that are for their benefit. I am concerned about those who are not responsible for reasons of dementia or a whole host of other, perhaps economics and they cannot perhaps buy the drugs that are required.

I can see a potential conflict between the vendors that have to cut 5 percent and the pharmaceutical companies who want to sell more drugs and perhaps the physician who has prescribed the drug that the benefit manager might try to cut out. I am not sure there is not some conflict brewing in that area. It is just this year, after 35 years or whatever it is, of Medicare that we decided to pay for an initial physical examination. In other words, Medicare beneficiaries were pretty much charged with going around and picking their own specialist if a specialist would take them without a referral because there was no way to get clocked into the system. I can

see the advantage of having Ask a Nurse or any of these benefit groups helping us along the way.

I guess my question to the physicians on the panel is, does the physician not have to start out by assessing a patient and determining what is wrong, how many of these diseases does this patient have, and what ought to be the plan? Is that not where it all starts, or am I missing something?

Dr. BUFALINO. I will be glad to answer that. I think you are absolutely right. The initial diagnosis is clearly made with the physician, either the family practice internist or a cardiologist, depending on the care loop. Those diagnoses are made and then a plan is laid out in terms of what needs to be done in terms of their therapy. So, most definitely.

Mr. STARK. That plan has to be designed by a physician, does it not?

Dr. BUFALINO. I think the initial plan, whether they are in the office or in the hospital is laid out by the physician. The question remains then is the follow-up, I think what Chairman Johnson was referring to, and the continuous loop. Although that initial interaction where we evaluate, decide the magnitude of their problem, do whatever diagnostic tests are necessary, the follow-up there is this chronic problem of trying to keep them out of the hospital.

I guess from our reading of a lot of the savings, it is about, can we keep folks at home with these chronic conditions as opposed to having them have to come back through the hospital because they did not take the right drug or did not take the right dose or had not had that close follow-up. Whether it be the physician or another entity, somebody needs to be watching that they are taking their medications properly, clearly.

Mr. STARK. Dr. Wright, what is your take on that?

Dr. WRIGHT. I would perish if someone took away my job of outlining a plan for my patient. That is the diagnostic and therapeutic process. Therapeutic process, that is what I do. I think the way I see disease management techniques benefiting just an average physician like me is to select data to record and report data for me that I do not have time or the inclination, but I desperately need in order to assess my own performance. I see them assisting in the notification and the execution of the plan that I have set up with my patient. I agree with you that there are tremendous hurdles, not just in the complexity of these medical problems, the number and complexity, but also in the patients who have the cognitive deficits.

Mr. STARK. Now, the practice of geriatrics, I guess, I was looking for their testimony which was submitted. Do they not attempt, the people who call them, whatever they call themselves, geriatrists?

Dr. WRIGHT. Geriatricians, I think.

Mr. STARK. Geriatricians. Is not that their role in a sense with old guys like me? Do they not say, okay, we are going to manage you, Stark, and look at you because you have problems at your age that younger people will not have. They are really, I hate to say "glorified internists;" that may be mean to somebody, but is that not their role then to refer them, if I have a heart problem, to you

all, or if I have sciatica, to send me to a neurosurgeon or to a physical therapist.

Dr. WRIGHT. I would have to tell you that at least in northern California, and I think this applies in more places, I also am a geriatrician because of the depth and breadth of cardiologic problems and because of the paucity of geriatricians in smaller communities. I would be delighted if someone came to town, but because of what I do every day, I am taking care of that population.

Mr. STARK. Go ahead.

Dr. BUFALINO. Your assessment is right. These are internists who specialize in patients over the age of 65 or over the age of 70. So, I think you are right on. Unfortunately, in our world, half of our patients are over the age of 65 just by the nature of heart disease.

Mr. STARK. Then I am getting that once you all have determined what the protocol for keeping all of my moving parts in working order should be, you turn to Ms. Selecky and say, here is the plan for Mr. Stark; will you guys call him, follow up. You have determined that I am not in very serious dementia, and I can answer the phone; and maybe somebody comes by the house and checks to see where the pill bottles are, and then they come back to you. Is that the way you see the system working?

Ms. SELECKY. Yes, thank you, Mr. Stark. My company was actually founded by a physician who was trying to find ways of delivering better care to his chronically ill patients, because these people have the disease 24 hours a day, 7 days a week, and the physician cannot be available all the time.

Mr. STARK. They can if you pay the $1,500 for the boutique kind.

Ms. SELECKY. What we do as an entity really is to support the physician's plan of care. We very strongly support the doctor-patient relationship. We understand what the plan of care is. We try to reinforce it with the patient to make sure they understand why their physician told them to do something, why it is important to follow through with that. We help remind them to do things that they need. To your earlier point about people with dementia and people who otherwise have trouble understanding the program, these people still have family members that need to care for them.

In the case where we cannot communicate directly with the patient, we communicate with their family member, because we are generally held accountable for the outcome of the entire population. Regardless of whether we can really engage that individual or not, we look for other ways of engaging them. So, there are a lot of things that we do to customize the program to the individual needs of our patient populations.

While we do provide services to the commercial, employed populations, I would say the majority of people we take care of are people more in their seventies and eighties and people who have very serious combinations of chronic conditions.

Mr. STARK. Thank you. I thank the panel very much.

Chairman JOHNSON. Thank you very much. This issue, the physician retaining control and that relationship with their patient, is of course central. You cannot have a health care system if you do not protect that relationship. I was very interested, Dr. Wright,

in your comments about these three doctors, and then the comments about follow on care even if it is just one doctor; this issue of continuous need for care and continuous need for care of patients with multiple illnesses. This RFP, what we started with was those seniors that have multiple chronic conditions, so we are starting with that group that go beyond the one physician but have three physicians who have gone through this care plan and made decisions; and how do we integrate those plans?

We also require everyone in the RFP to deal with patients who are cognitively impaired because there is no sense in learning how to do all of this when half of the population of our retirees have some level of cognitive compromise. So, we do need to learn that from the ones that are totally compromised to the ones that are just partially compromised. Recognizing the real dearth of geriatric physicians, we did have two of the demonstrations, I think it is two, specifically focused on: how do you couple a geriatric center capability with, particularly, small-practice physician capability? Because there the practicing physician is making the plan, and we are going to create a collaborative organization to oversee the implementation of that plan when there are multiple illnesses involved, but having that geriatric capability to look at that situation is going to be very useful to us. How do we spread the power of the geriatrician over a larger number of physicians, since there is never going to be a geriatrician in every community even as our population ages?

So, I just wanted to clarify that, that the RFP is about multiple illness and involves people with cognitive problems so that we will get the full variety of solutions out there to this challenge. Mr. Crane.

Mr. CRANE. Thank you, Madam Chairman. Dr. Wright, when you were reminiscing about your dad being a physician, it reminded me of my own personal experience. My dad got his first doctorate in psychology and he was treating at Northwestern. My mom went into labor on a Saturday and the obstetrician was out of town. So, my dad said he put newspapers on the bed and started boiling water and had the dog come in and sit at my mother's side and he delivered me. I said, Pop, were you not a little intimidated by that? He said, oh, we delivered pigs and cows at the farm; it was no big deal.

Then he got his medical doctorate and he delivered the next three of my siblings at home on purpose. He used to do surgery on the dining room table. My great-grandmother, when she was 92, had cataracts in both eyes, and he operated on one and restored her vision in one eye. We were excited to hear about that, and we said, well, that is just one eye. Are you not going to do the other? He said that she is 92. All she needs is one.

Dr. WRIGHT. Cost conscious even then.

Mr. CRANE. I could not follow in his footsteps. I could not even stand to look at a needle going in your skin and my kid brothers got their doctorates, one dentist and one physician, but I was overwhelmed by that sort of thing. I still reminisce for entertainment purposes about those years growing up.

I would like to ask you one question about your testimony. You discussed the success of the cardiac rehabilitation program. Can

you provide some insights as to why these programs have been so successful and what lessons from them should be incorporated into the CCIP and Medicare?

Dr. WRIGHT. Thank you, I would love that opportunity. I learn, I hope, I am getting wiser with time. I did not understand why I had always been interested in cardiac rehab, and then when disease management came across the radar, it struck me as something that was fascinating and important. It was not until I tried to put this essay together—it has been a while since I have written an essay, by the way—that I realized how linked they are, that cardiac rehab is actually one of the original disease management programs.

I think there are many parallels between the successful programs that we have come to see in the medical care system, that we see right now, and the original one. Cardiac rehab, first of all, is based in science and it is successful because it builds personal relationships. When a sick person knows that the person caring for them is invested in them, actually cares about the outcome, and that contact is not continuous but frequent, and that the medical care person is well informed about the specifics of that person's medical situation, that is a very powerful mechanism for healing. I think that is what cardiac rehab does.

It is so much more than an exercise program. It actually allows surveys of that patient's medical world, if you will, their environment, so that if a patient who has a recent angioplasty, starts to have a little chest discomfort on the track, the patient already has a contact with the nurse, the nurse already knows what that patient looks like going around the track, and when he or she starts to look a little different, questions are asked. Immediately we know that something is brewing and the patient gets referred early and the patient gets restudied or stented, restented, whatever the situation is.

So, it works for prevention. It works for disease surveillance and treatment. It reinforces that the medical care system is designed to deliver medical care through to each individual according to his or her needs.

Mr. CRANE. Ms. Selecky, in your testimony, you talk about the different ways that organization will partner to respond to the RFPs. Given the objectives of the RFP and the unique needs of Medicare beneficiaries with multiple chronic conditions, do you believe that an approach involving multiple organizations will be necessary and do you think such consortia can be successful?

Ms. SELECKY. I think that what is necessary is understanding that disease management is really about creating a team environment to take care of people. People who have chronic disease, as we have already talked about here, not only have several different physicians, but there are a lot of people who are involved and a lot of entities that are involved in trying to make them successful in managing their health.

Really, what disease management organizations are about is trying to defragment that system and make kind of a central location for all of that information and all of those efforts to be coordinated. So, it is very important that we not view this as an opportunity for any particular kind of an entity to be successful here. I think what

is important is that all of these efforts really reach out and make an effort to connect the different entities in the health care system.

That being said, I think that what is important in this is really that the programs and the groups of providers and suppliers and whatever that come together to do these programs really understand what their role is and that there is good data integration among them and they come with some proven outcomes, that they can actually show CMS that the approach that they are going to take is going to be one that will enhance the outcomes for the beneficiaries as well as reduce cost.

Mr. CRANE. Very good. Now, my neighbor, I would like to ask you this final question here. Dr. Bufalino, throughout your testimony you discussed the need for evidence-based performance measurements to evaluate quality of care and beneficiary satisfaction. Can you discuss further the types of measurement that CMS might want to consider in reaching agreements with bidders under the CCIP?

Dr. BUFALINO. Thank you. I think it is a complex issue. They already have in the RFP a number of quality measures, and many of them are physician—driven. They are the assessment of that patient's heart muscle function.

If we talk about heart failure, which is my area of interest, and the measure of are they on the right drugs, is their blood pressure controlled, how often are they hospitalized, how often are they rehospitalized, how many trips do they make to the emergency room, those are all measures there.

I think we would love to have the opportunity at the AHA, involved with the National Quality Forum, to help set some further outcomes, the opportunity to take science and give some meaningful measures. We want to know that these patients have better quality of life because of this program. Do they feel better? Are they able to spend more time with their family? Are they able to function at a higher level is important as part of this measure. Also, do they live longer? As much as this is a chronic disease and we are talking about do we keep them out of the hospital, do we prolong their lives is a critical question for us in terms of the benefits.

I think those are important things, and we would like to participate in an opportunity that helps set those clearly science-based outcomes because we think there is an opportunity to make this meaningful. I think the Chairman has made it very clear here that this is about doing a better job, and we would love to participate in this. Our goal as physicians, or part of the organizations we are involved in is, how do we reduce death and disability from this disease? We still lost a million lives last year to heart disease, a huge problem. We have about 4.5 million folks in the country with heart failure. So, we can use all the help we can get, quite frankly. I think our plea is that we would like to be involved in helping improve those outcomes. I think there is a tremendous opportunity there to work on this together.

Mr. CRANE. Thank you very much. I thank all three of you for your testimony, and we look forward to working with you in the future.

Chairman JOHNSON. I thank you all for being with us here today. I hope as we work on this together and we see how these pilots work and we combine our experience now in the government arena with your experience as practicing physicians, we can within the near future develop a sounder approach to encouraging coordinated care and integrated care in our health system systematically.

I would also ask that you think, because all of you are where these decisions are made, what are we going to draw from this in terms of helping patients deal with end-of-life care decisions? Because we cannot continue—this is my personal opinion; this is nobody else's opinion; this does not come from the Subcommittee. If we are going to serve twice as many seniors in the future, we have to enable them to live a healthier life, and this is crucial to that. We have to get them more involved in their health care, and this will do that.

We also have to more intelligently understand the declining process and at what point does one really look for just palliative care, supportive care, those kinds of support systems that recognize that we are now in a different era of medical experience and personal experience. So, we need to think about, how does disease management better prepare us for understanding when the disease process is reaching a point at which it has a logic of its own and interventions are of little human value and of great social cost? So, I do not ask you to respond to that.

Ms. SELECKY. I could though, Chairman Johnson, if you do not mind. I think, speaking to what Dr. Wright said earlier, it is about the personal relationships that you build with your patients and, in our case, with our program participants. That whole process is also a team approach where you have family members and physicians.

Chairman JOHNSON. Are you seeing some of that?

Ms. SELECKY. We see much of it because we take care of tens of thousands of people with congestive heart failure, and it is a terminal disease. We do end up spending a lot of time working with people, to have them understand what the consequences are of their condition; and as it appears that that might be something that we need to help them with, we refer them to hospice programs. We talk to them about living wills. We talk to them about advance directives. I tell you, it is always very sad when one of our program participants passes away, but we have many cases in which their family members have called us afterward and thanked our nurses for the care and consideration that they have shown them. So, it is a process. It is about trying to make people's quality of life better regardless of what that quality of life entails.

Chairman JOHNSON. Do either of you want to comment?

Dr. BUFALINO. Two ends of the spectrum: I think the one thing that the MMA saw, very importantly, was to do a preventive piece, which we were missing, the idea to do screenings and get this disease early so we can do something about it. We have the tools and the ability to make a difference. We just sometimes do not get the chance.

So, to prevent heart failure before it happens is where there is a huge savings to the country, and to that individual patient obviously.

On the other end, I think it is fascinating to see the difference—and I think you are very insightful on your comments about having people be comfortable when the end is near, and that really comes with that physician-patient relationship and with the family.

I am sure Janet has the same experience to be able to sit and talk to that family and say, you know what, we have done everything we could for Grandma; I think we should keep her comfortable. I find many, many more patients today and their families much more comfortable with that decision than there were 10 or 15 years ago. They know where this could go and the outcome is not likely to be any better.

Heart failure is cancer of the heart. We just call it something different. It is a terminal disease. So, we prepare them from the beginning, once that diagnosis is made, that there is only so much we will be able to accomplish. We do want to keep them comfortable, but we need to decide when we have done all we can do.

Dr. WRIGHT. I do not have anything else. They have said it and said it beautifully, and I do appreciate your interest in this also. I do not think we have done as good of a job as we should, but I would like to just add two quick thoughts about this legislation. Frankly, Chairman Johnson, hearing you speak about the potential impact for it and seeing your dedication and that of the Committee, it has given me hope.

I did not tell you that my dad was disappointed when I went into medicine. He told me not to because the government was going to meddle in it, and I would not be able to enjoy practicing. I am glad I ignored him. It is the only piece of advice I ignored.

My hope is that what we have seen happen with women's health will happen with chronic disease health. By that I mean, in the early days of doing cardiology, we knew that women were dying, but we did not understand why. We did not understand that they were actually different than men. It sounds like such a novel thought.

Women were not part of the research protocols, not because of a gender bias, but because women are hard to study. You cannot pick a research subject that is literally, from day to day, might be pregnant or might be nursing or in the menopause years, a period of 5 or 6 years. The woman is different literally from day to day; I can testify to that.

So, women were not selected for research until this body, until Congress said, you will include women; they are tough research subjects, but you will include them; we mandate that so we can learn about them. As a result, we have a flood of information. We have learned so much that will protect women and prevent heart disease, not to mention all the other problems, as a result of the action of this body. I have the same hope that this legislation and its implementation will create that kind of transformation in the care of older people with multiple diseases.

Chairman JOHNSON. Thank you. I think we are capable of that and we are capable of some other alternatives which I hope to block. So, I appreciate your testimony today. This is a challenging time. It is an exciting time both in medicine and in government policymaking. I thank you for your participation in the process, in being with us today. Thank you. The hearing is adjourned.

[Whereupon, at 4:00 p.m., the hearing was adjourned.]
[Submissions for the record follow:]

Statement of AdvaMed

AdvaMed is pleased to provide this testimony on behalf of our member companies and the patients and health care systems we serve around the world. AdvaMed is the largest medical technology trade association in the world, representing more than 1100 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $71 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $169 billion purchased annually around the world.

Significant advances in health care technologies—from health information systems that monitor patient treatment data to innovative diagnostics tests that detect diseases early and lifesaving implantable devices—improve the productivity of the health care system itself and vastly improve the quality of the health care delivered. New technologies can reduce medical errors, make the system more efficient and effective by catching diseases earlier—when they are easier and less expensive to treat, allowing procedures to be done in less expensive settings, and reducing hospital lengths of stays and rehabilitation times.

AdvaMed would like to thank the Congress for passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108–173). We share your goals for the new law to make the Medicare program more efficient and effective for providers and Medicare beneficiaries. We believe it is in the best interest of patients and the Medicare program to have the system capitalize on advanced technologies, which have revolutionized the U.S. economy and driven productivity to new heights and new possibilities in many other sectors.

Chronic Care Improvement Programs: Improving Patient Care and Modernizing Medicare

AdvaMed strongly supported the inclusion of the Chronic Care Improvement Program (CCIP) in the MMA to establish a voluntary pilot program in fee-for-service Medicare focusing on congestive heart failure, diabetes, and chronic obstructive pulmonary disease. If designed appropriately, coordinated care for patients with chronic conditions and diseases will keep patients healthier and happier, as well as reduce the number of expensive hospital visits from complications related to the chronic illnesses.

In fact, a report published in February 2004 by MEDTAP international entitled *"The Value of Investment in Health Care: Better Care, Better Lives,"* shows the benefits of investing in health care far outweigh the costs, and it measures those benefits in human and economic terms. The study shows from 1980 to 2000 that each additional dollar spent on health care in the U.S. produced tangible health gains of $2.40 to $3. Overall findings by the year 2000 show that annual mortality rates declined 16%; disability rates declined 25%; life expectancy increased 4%, or 3.2 years; and hospital days fell 56%. In the four major diseases studied, the report finds in the year 2000, mortality from heart attack was cut almost in half; deaths from stroke were cut by over one third; breast Cancer mortality declined 20%; and diabetes management improved dramatically and produced a 25 percent reduction in complications such as blindness, kidney failure, stroke and death.

The Important Role of Technology in Designing a Successful CCIP

AdvaMed is monitoring implementation of the CCIP to ensure that it delivers the value promised to Medicare beneficiaries by the Members of this subcommittee who crafted the pilot program. In choosing organizations to participate in the pilot program, CMS should consider an organization's ability to integrate a range of technologies into its proposed chronic care improvement program. Such technologies include, but are not limited to, remote monitoring devices, implantable devices, and information technology-based solutions. In addition, CMS should set per patient per month fees paid to organizations at a rate sufficient to cover the costs of the technologies and the staff necessary to employ them.

We worked closely with CMS in between passage of the MMA and the issuance of the Request for Proposals (RFP) on April 20th and have provided comments to CMS with our specific concerns and questions about the RFP. Specifically, clinical management of patients with multiple, progressive, chronic conditions—such as complex diabetes, congestive heart failure, and chronic obstructive pulmonary disease—often requires intensive monitoring and intervention. However, the CMS solicitation for the CCIP states that there will be no change in the amount, duration, or scope of a participant's fee-for-service Medicare benefits. AdvaMed seeks clarifica-

tion from CMS as to whether existing Medicare Part B utilization controls will be modified or suspended under the CCIP. We are concerned that requiring awardees to reduce preventable hospitalizations, health care costs, and adverse health outcomes, in the context of an acute care-oriented program in which strict utilization controls continue to be enforced, could frustrate the purpose of the CCIP.

For example, in an attempt to obtain and maintain tighter glycemic control, an organization might require certain patients with complex diabetes to perform blood glucose self-monitoring more often than current Medicare policies allow. Under current Medicare program guidelines, without additional medical necessity documentation, Medicare Part B reimbursement for blood glucose reagent strips and lancets is limited to 100 every three months in patients with noninsulin-treated diabetes. Instead of a rigid formula, CMS should provide CCIP contractors sufficient flexibility to maximize patient outcomes.

In addition, as part of the per patient per month fees, organizations submitting bids must include the costs of services not currently covered by Medicare. CMS has left it unclear how these organizations should treat services for which the coverage varies by local carrier.

Lastly, under the CCIP, organizations will be financially at risk for their fees if they fail to meet agreed upon performance guarantees for clinical quality, beneficiary and provider satisfaction, and savings targets. Notwithstanding the enforcement role of the threat of financial penalties, it would be in the best interests of the beneficiaries and organizations alike if the organizations' programs improve themselves throughout the duration of the CCIP to increase the chances of executing Phase II. Therefore, AdvaMed has requested that CMS consider requiring each organization, as part of its beneficiary satisfaction and quality assurance measures, to establish an internal Beneficiary Ombudsman. The Ombudsman would ensure a clear channel of communication between beneficiaries and the organization, as well as provide the organization with a check on the quality of care that its beneficiaries are receiving.

Conclusion

AdvaMed thanks the Subcommittee members again for their collaborative efforts to improve and strengthen the Medicare program. We look forward to working with the Administration and this Committee on designing a comprehensive and successful CCIP to improve the quality of care for Medicare patients.

Statement of the Alzheimer's Association

Since our founding in 1980, the Alzheimer's Association has provided more than $150 million to support research into the prevention, treatment and eventual cure for Alzheimer's. Our nationwide network of chapters offer frontline support to individuals affected by Alzheimer's with services that include 24/7 information and referral, safety services, and education and support groups.

Section 721 of *the Medicare Prescription Drug, Improvement, and Modernization Act* authorizes Chronic Care Improvement Programs that will focus on one or more of three threshold conditions: congestive heart failure (CHF), diabetes, and chronic obstructive pulmonary disease (COPD). The Act requires entities that implement a Chronic Care Improvement Program to "have a process to screen each targeted beneficiary for conditions other than threshold conditions, such as impaired cognitive ability and other comorbidities, for the purpose of developing an individualized, goal-oriented care management plan."

When Alzheimer's disease is present, the Medicare costs of already-expensive conditions like COPD, congestive heart failure or diabetes double. The attached fact sheets show: 1) the proportion of Medicare beneficiaries with each of the threshold conditions who also have Alzheimer's disease and other dementias; and, 2) the impact of coexisting Alzheimer's and other dementias on total Medicare expenditures and hospital use for beneficiaries with the threshold conditions. Although it might be assumed that older average age of beneficiaries with the threshold conditions plus Alzheimer's or other dementias explains the higher Medicare expenditures and hospital use, data presented in the fact sheets show that this is not true. In fact, the difference between average Medicare expenditures for beneficiaries with any of the threshold conditions plus Alzheimer's or other dementias vs. beneficiaries with the threshold condition but no Alzheimer's or dementia is greatest in the youngest age group (beneficiaries age 65–74).

Entities that implement Chronic Care Improvement Programs should have procedures in place to accurately identify Alzheimer's and dementia in their program participants. In addition, these entities should have procedures in place for developing and implementing a care management plan that takes into account the effects of Alzheimer's and dementia-related cognitive impairment on a person's ability to follow treatment recommendations, take medications as prescribed, and manage other aspects of his or her care. These entities should have procedures for identifying a family caregiver, if any, and managing care for participants with Alzheimer's and other dementias who do not have family caregivers.

Patient self-care and self-management approaches, which are used in many disease management programs are unlikely to be effective for many program participants with Alzheimer's and other dementias. The entities that implement the Chronic Care Improvement Programs will have to adapt these approaches for participants with Alzheimer's and dementia. Use of community services, including Alzheimer's Association chapter services, is likely to improve outcomes for program participants with Alzheimer's and other dementias. The entities that implement the Chronic Care Improvement Programs will have to develop effective ways of linking program participants with Alzheimer's and dementia to these essential services.

Medicare Beneficiaries with Congestive Heart Failure And Co-existing Alzheimer's Disease or Other Dementias

Prevalence of co-existing Alzheimer's disease and other dementias in Medicare beneficiaries with congestive heart failure (CHF)

Medicare claims data for a 5% national random sample of fee-for-service Medicare beneficiaries age 65+ indicate that in 1999, 11% of these beneficiaries had CHF. Of the beneficiaries with CHF, 21% also had Alzheimer's disease or other dementias (AD/D). In 2000, 12% of Medicare fee-for service beneficiaries age 65+ had CHF, and 21% of these individuals also had AD/D.[1]

Medicare expenditures and hospitalizations for beneficiaries with CHF and co-existing Alzheimer's and other dementias

In 1999, average Medicare expenditures and hospital use were substantially higher for beneficiaries with CHF and AD/D than for beneficiaries with CHF but no AD/D.

- Total average per person Medicare expenditures for those with CHF and AD/D were 47% higher than for those with CHF but no AD/D ($22,459 vs. $15,271).[1]
- Average per person Medicare hospital expenditures for those with CHF and AD/D were 40% higher than for those with CHF but no AD/D ($13,210 vs. $9,414).[1]
- Medicare beneficiaries with CHF and AD/D were almost twice as likely as those with CHF but no AD/D to be hospitalized and almost twice as likely to have a preventable hospitalization.

In 2000, total average Medicare expenditures and average hospital expenditures were about 50% higher for those with CHF and AD/D than for those with CHF but no AD/D.[1]

Increased expenditures for CHF with Alzheimer's disease and other dementias are not explained by older age

Total Medicare expenditures for Beneficiaries with CHF by AD/D Status and Age[1]

Age	Beneficiaries with CHF and no AD/D	Beneficiaries with CHF and AD/D	% Increase associated with AD/D
65–74	$17,993	$34,304	91%
75–84	15,515	25,368	64%
85 and over	11,947	17,632	48%

Medicare Beneficiaries with Diabetes And Co-Existing Alzheimer's Disease or Other Dementias

Prevalence of co-existing Alzheimer's disease and other dementias in Medicare beneficiaries with diabetes

Medicare claims data for a 5% national random sample of fee-for-service Medicare beneficiaries age 65+ indicate that in 1999, 16% of these beneficiaries had diabetes.

Of the beneficiaries with diabetes, 11% also had Alzheimer's disease or other dementias (AD/D). In 2000, 17% of Medicare fee-for-service beneficiaries age 65+ had diabetes, and 12% of them also had AD/D.[1]

Medicare expenditures and hospitalizations for beneficiaries with diabetes and co-existing Alzheimer's and other dementias

In 1999, average Medicare expenditures and hospital use were much higher for those with diabetes and AD/D than for beneficiaries with diabetes but no AD/D.

- Total average per person Medicare expenditures for those with diabetes and AD/D were 144% higher than for those with diabetes but no AD/D ($19,395 vs. $7,940).[1]
- Average per person Medicare hospital expenditures for those with diabetes and AD/D were 163% higher than for those with diabetes but no AD/D ($11,192 vs. $4,254).[1]
- Medicare beneficiaries with diabetes and AD/D were 3 times as likely as those with diabetes but no AD/D to be hospitalized and more than three times as likely to have a preventable hospitalization.[2]

In 2000, total average Medicare expenditures were 150% higher and average hospital expenditures were 160% higher for those with diabetes and AD/D than for those with diabetes but no AD/D.[1]

Increased expenditures for diabetes with Alzheimer's disease and other dementias are not explained by older age

Medicare beneficiaries with diabetes and AD/D are older on average than those with diabetes but no AD/D. In 2000, 29% of those with diabetes and AD/D were age 85+ compared with only 8% of those with diabetes but no AD/D;[1] however, older average age does not explain the higher Medicare expenditures for those with diabetes and AD/D. In fact, the difference between average Medicare expenditures for those with diabetes and AD/D vs. those with diabetes and no AD/D was greatest for beneficiaries age 65–74.

Total Medicare Expenditures for Beneficiaries with Diabetes by AD/D Status and Age, 2000

Age	Beneficiaries with diabetes and no AD/D	Beneficiaries with diabetes and AD/D	% Increase associated with AD/D
65–74	$7,469	$24,392	227%
75–84	8,563	19,920	133%
85 and over	8,979	16,569	85%

Medicare Beneficiaries with Chronic Obstructive Pulmonary Disease And Co-existing Alzheimer's Disease and Other Dementias

Prevalence of co-existing Alzheimer's disease and other dementias in Medicare beneficiaries with chronic obstructive pulmonary disease (COPD)

Medicare claims data for a 5% national random sample of fee-for-service Medicare beneficiaries age 65+ indicate that in 1999, 10% of these beneficiaries had COPD. Of the beneficiaries with COPD, 15% also had Alzheimer's disease or other dementias (AD/D). In 2000, 10% of Medicare fee-for-service beneficiaries age 65+ had COPD, and 15% of them also had AD/D.[1]

Medicare expenditures and hospitalizations for beneficiaries with COPD and co-existing Alzheimer's disease and other dementias

In 1999, average Medicare expenditures and hospital use were substantially higher for beneficiaries with COPD and AD/D than for beneficiaries with COPD but no AD/D.

- Total average per person Medicare expenditures for those with COPD and AD/D were 93% higher than for those with COPD but no AD/D ($23,614 vs. $12,220).[1]
- Average per person Medicare hospital expenditures for those with COPD and AD/D were 90% higher than for those with COPD but no AD/D ($14,225 vs. $7,472).[1]
- Medicare beneficiaries with COPD and AD/D were twice as likely as those with COPD but no AD/D to be hospitalized and almost twice as likely to have a preventable hospitalization.[2]

In 2000, average Medicare expenditures were 90% higher and average hospital expenditures were 84% higher for those with COPD and AD/D than for those with COPD but no AD/D.[1]

Increased expenditures for COPD with Alzheimer's disease and other dementias are not explained by older age

Medicare beneficiaries with COPD and AD/D are older on average than those with COPD but no AD/D. In 2000, 32% of those with COPD and AD/D were age 85+ compared with only 12% of those with COPD but no AD/D;[1] however, older average age does not explain the higher Medicare expenditures for those with COPD and AD/D. As shown below, the difference between average Medicare expenditures for those with COPD and AD/D vs. those with COPD and no AD/D was greatest for beneficiaries age 65–74.

Total Medicare Expenditures for Beneficiaries with COPD by AD/D Status and Age, 2000

Age	Beneficiaries with COPD and no AD/D	Beneficiaries with COPD and AD/D	% Increase associated with AD/D
65–74	$12,059	$28,463	136%
75–84	12,782	24,416	91%
85 and over	12,847	19,557	52%

REFERENCES

[1] These figures come from FY 1999 and FY 2000 Medicare claims for a 5% national random sample of fee-for-service Medicare beneficiaries age 65+. Those with no claims are included. Medicare beneficiaries who were enrolled in Medicare managed care and beneficiaries under age 65 are excluded. Beneficiaries were classified as having COPD based on Clinical Classification Software (CCS) categories. Beneficiaries were classified as having AD/D if they had at least one Medicare claim with an ICD–9 code diagnosis 290, 294, or 331 in the relevant year.

[2] Bynum JPW, Rabins PV, Weller W, et al., "The Relationship Between a Dementia Diagnosis, Chronic Illness, Medicare Expenditures, and Hospital Use," *Journal of the American Geriatrics Society,* 52(2):187–194, 2004.

Statement of Virginia Zamudio, American Association of Diabetes Educators, Chicago, Illinois

Thank you, Chairwoman Johnson, Ranking Member Stark, and members of the Subcommittee, for holding this important hearing today on the newly instituted Medicare Chronic Care Improvement Program (CCIP). I am Virginia Zamudio and I am a registered nurse, certified diabetes educator, and President of the American Association of Diabetes Educators. On behalf of AADE, a group of health care professionals dedicated to improving the care of people living with chronic disease, I am submitting this written testimony to express our strong support for the CCIP and to suggest additional measures the Committee should consider in its efforts to strengthen the Medicare program to improve care for beneficiaries with diabetes.

About the American Association of Diabetes Educators

Founded in 1973, the American Association of Diabetes Educators is a multi-disciplinary professional membership organization dedicated to advancing the practice of diabetes self-management training and care as integral components of health care for persons with diabetes, and lifestyle management for the prevention of diabetes.

AADE's more than 10,000 members are healthcare professionals who are members of the diabetes care team. They include nurses, dieticians, pharmacists, physicians, social workers, exercise physiologists and other members of the diabetes teaching team. AADE currently has 105 local chapters and 17 specialty practice groups.

The Burden of Chronic Disease

Chronic diseases such as heart disease, diabetes, and cancer are the leading cause of death in the United States, killing seven out of ten Americans. The costs of chronic disease are staggering—more than 75 percent of health care expenditures in the United States are for chronic illness. And that figure is expected to grow. By 2020, $1 trillion, or 80 percent of health expenditures, will be spent on chronic diseases. More than 125 million Americans live with some form of chronic disease, and millions of new cases are diagnosed each year. The challenges of treating chronic dis-

ease are myriad—patients often have more than one chronic condition and therefore see multiple health care providers. This results in un-coordinated care, duplicitous and sometimes contradictory treatment plans, and healthcare inefficiencies.

Chronic diseases are especially burdensome in the Medicare program. Beneficiaries with more than five chronic conditions account for only 20 percent of the Medicare population, yet 66 percent of Medicare's budget is spent treating these individuals. We can and should do more to improve disease management programs under the Medicare program.

The Burden of Diabetes

Diabetes poses a particular burden for the Medicare program. As you know, diabetes is a serious, debilitating chronic illness that afflicts more than 18 million Americans, including eight million Medicare beneficiaries. An additional eight million seniors suffer from a condition known as "pre-diabetes" that, when left untreated, will develop into diabetes.

Diabetes' devastating complications—kidney failure, blindness, lower extremity amputation, heart disease and stroke—result in significant costs to the program. Although beneficiaries with diabetes comprise only 20 percent of the Medicare population, spending on diabetes related complications account for more than 30 percent of expenditures. With the current obesity epidemic, the aging of the baby boom generation, and the expected growth in numbers of Medicare beneficiaries with diabetes, the cost of diabetes related complications could seriously undermine the financial stability of the Medicare program.

The Value of Diabetes Self Management Training

While the costs and complications of diabetes are daunting, there is much that can be done to prevent diabetes and reduce its complications. Patient self-management is cornerstone of chronic disease care, and in no case is that more true than diabetes self-management. Diabetes self-management training (DSMT), also called diabetes education, provides the skills that patients with diabetes need to successfully manage their illness. DSMT helps patients identify barriers, facilitate critical thinking and problem solving and develop coping skills to effectively manage their diabetes. Initial diabetes self-management training occurs over a four to six month period, with additional follow-up as needed.

The goal of diabetes self-management training is to achieve measurable behavioral change outcomes in areas such as physical activity; meal planning; medication administration; blood glucose monitoring; problem solving for high and low blood glucose and sick days; reducing risk factors for diabetes-related complications; and living with diabetes/psychosocial adaptation. National standards for Diabetes Self-Management Programs were established in the 1980s.

Certified Diabetes Educators (CDEs) are highly trained healthcare professionals—often nurses, pharmacists, or dieticians—who specialize in helping people with diabetes develop these skills. To earn the CDE designation, a health care professional must be licensed or registered, or have received an advanced degree in a relevant public health concentration, have professional practice experience and have met minimum hours requirements in diabetes self-management training, and have met certification and recertification requirements.

The value of DSMT is well documented. The Diabetes Prevention Program study of 2002 demonstrated that participants (all of whom were at increased risk for developing type 2 diabetes) were able to reduce that risk by implementing the lifestyle changes taught as part of DSMT. Additional studies have found that patients with diabetes achieved significantly better outcomes when part of comprehensive diabetes management programs.

Diabetes Self Management Training and the Medicare Program

The Chronic Care Improvement Program is an important measure aimed at improving the quality of care for chronically ill beneficiaries under Medicare fee-for-service. While we support this effort, we feel it is important to note that this is not the first time that Congress has attempted to improve disease management for beneficiaries with diabetes.

Congress recognized the value of DSMT when it enacted the Balanced Budget Act (BBA) of 1997. Section 4105 of BBA provided coverage and reimbursement for DSMT by physicians and other individuals or providers who were eligible to bill Medicare for services or supplies, provided that DSMT was furnished incident to other covered services, regardless of whether those items or services are related to diabetes care.

Under current law, all recognized providers can bill Medicare for DSMT, provided CMS guidelines and American Diabetes Association education recognition criteria are met. Because Certified Diabetes Educators are not recognized as Medicare pro-

viders, however, they are precluded from directly billing Medicare for DSMT. They must bill either through a hospital-based program or through a physician's office. We believe that it is counterintuitive and counterproductive to exclude the group of health care providers that are most skilled and capable of providing this critical benefit.

This provision could also seriously threaten beneficiary access to DSMT. As it is, the Centers for Medicaid and Medicare Services (CMS) reports that the DSMT benefit is underutilized—only 30 percent of eligible beneficiaries are receiving DSMT. This situation is likely to grow worse, however, as hospital based DSMT programs are closing at a rate of 2–5 per month. Absent legislative action, fewer and fewer Medicare beneficiaries will be able to access the services of a CDE.

H.R. 3194, introduced by Congressman Curt Weldon and Congresswoman Diana DeGette, would correct this problem by recognizing CDEs as providers under the Medicare program. This legislation would help realize Congress' intent in BBA, which was to expand access to DSMT programs for all beneficiaries with diabetes. As this committee considers ways to improve disease management for patients with chronic illnesses, we strongly recommend the enactment of H.R. 3194.

Conclusion

In conclusion, we wholeheartedly support efforts to improve diabetes care, such as CCIP. We feel it is incumbent upon the Congress, however, to ensure that measures already in place to improve diabetes care—such as the DSMT benefit—are strengthened so that beneficiaries with diabetes can gain the critical skills they need to manage their illnesses.

Thank you, Madam Chairwoman, for allowing AADE this opportunity to express its concerns. We welcome the opportunity to work with you, and this Subcommittee, to further our mutual goals of improving diabetes care under the Medicare program.

Statement of the American College of Physicians

The American College of Physicians (ACP), representing over 115,000 internal medicine physicians and medical students, is pleased to provide written comments on Section 721 of the Medicare Modernization Act of 2003, the Medicare Chronic Care Improvement (CCI) demonstration program. These comments are provided in follow-up to the May 11, 2004 hearing on the CCI program held by the Subcommittee on Health of the House Ways and Means Committee.

1. ***Care for Chronically Ill Medicare Patients with Multiple Co-Morbid Conditions is Fragmented and Unduly Costly Under Medicare Fee-for-Service, Making CCI Pilot Testing Crucial for Medicare's Future***

The CCI program represents an attempt to study the cost-effectiveness, quality of care outcomes, and provider and patient satisfaction which may result from using a coordinated care approach for selected chronically ill Medicare patients. According to the Centers for Medicare and Medicaid Services (CMS), while Medicare patients with 5 or more chronic conditions represent 20 percent of the total Medicare population, this group represents 66 percent of all Medicare spending, making it vital that their care be more cost-effective. The CCI program's initial focus on patients with congestive heart failure or complex diabetes is a recognition by CMS that these beneficiaries have exceptionally high self-care burdens and high risks of experiencing poor clinical and financial outcomes.

Case management of the care of chronically ill Medicare patients is a vital, high level service which, until now, has not been duly recognized and compensated under Medicare fee-for-service (FFS). Yet, there is accruing evidence that case management of the chronically ill can have a significant positive impact on the quality of patient care and reduce costs, when compared to receiving care in a fragmented, hit-or-miss fashion under Medicare FFS.

In a January 2004 Issue Brief, Georgetown University's Center on an Aging Society concludes that "disease management programs can reduce health care use and expenditures" by being "successful at improving self-care practices and reducing use of various health care services, including hospital admissions and emergency room visits. As a result, health care expenditures for certain populations with chronic conditions have decreased."

The Disease Management Association of America (DMAA), in a paper titled, "The Benefits of Disease Management in Medicare and Medicaid," cites evidence of how disease management improves quality of care and lowers cost. These positive find-

ings led to DMAA's statement that it "fully supports and commends the Congress and CMS for promoting the expansion of disease management programs in its efforts to modernize and revitalize Medicare+Choice and through coordinated care provisions of the Medicare, Medicaid, SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), and other demonstration projects."

Unlike a number of other CMS chronic care demonstration programs, which are experiments with no statutory requirement for later adoption, the CCI program is intended to identify new approaches to coordinating and paying for chronic care case management which ultimately will become a permanent part of Medicare. As such, ACP applauds Congress's willingness to use the CCI pilots to determine which models of care oversight work best for chronically ill patients, in terms of cost-effectiveness and improved patient outcomes, and then implement them nationally for the benefit of all Medicare patients.

2. ***Internists Are Best Suited to Lead and Oversee the Care of Chronically Ill Patients***

ACP believes strongly that a physician skilled in the management of multiple chronic adult illnesses should lead the care management team. Only doctors of internal medicine are specially trained and experienced in caring for these complex patients. By using a patient-centered, physician-guided approach to care, all elements of care are supervised and monitored by a single responsible medical expert, who places the patient's well being at the heart of care. Not only does this permit much tighter coordination of a patient's care than is possible with a disease management (DM) organization, the physician team leader is free to make the best choices for high quality efficient care for their patients, without profit motives which impact clinical decision making.

3. ***A Patient-Centered, Physician-Guided CCI Pilot Model Should Include a Physician Case Management Fee and Incentives for Performance***

It is ACP's position that the heightened responsibility of this physician team leader position, as well as its potential to produce better patient outcomes at lower cost, clearly warrant an augmented payment to physicians for the extra coordination work this entails, as well as an additional incentive payment for improved patient outcomes and lowered costs.

ACP's position on the importance of using a patient-centered, physician-guided model which is linked to payment incentives is echoed loudly in the testimony of Robert A. Berenson, M.D., Senior Fellow at the Urban Institute, provided to the Subcommittee on Health on May 11, 2004:

> "Although the CCI program may be a good start, in my opinion it is insufficient for truly addressing chronic care needs in Medicare because it lacks a focused physician component . . . The financial underpinnings of a typical medical practice do not support physicians who actually do recognize the need to be more fully engaged in the components of chronic care coordination—Bounced around the system, too many Medicare beneficiaries do not even recognize a particular physician who is responsible for coordinating their care—Among other areas that need attention is the overlooked issue of physician payment policy. Simply put, the incentives inherent in most fee-for-service payment systems, including Medicare's and those of most private payers, penalize primary care physicians who would alter their professional interactions with patients to respond to the challenge posed by the reality of patients with multiple complex conditions. Yet, the Medicare Modernization Act mostly ignores alternative payment approaches affecting physician behavior. These payment approaches should go hand in hand with the new chronic care program to ensure the kind of change needed to improve care for Medicare beneficiaries."

ACP agrees strongly with the CCI program's provision of a per enrollee per month case management fee to organizations winning CCI contracts with CMS. However, since these fees are paid to the contractors, we would urge CMS ensure that, wherever a physician case manager is the head of the care delivery team, that participating organizations be required to share this fee with their physician case managers

The CCI program's RFP also does not explicitly call for or preclude contractors from paying performance bonuses to their physician case managers. The major issue is that contractors' are at risk for their case management fees, meaning if negotiated health improvement targets for their chronic care enrollees are not met in terms of cost savings, the shortfalls will be taken out of their case management fees. Considering the novelty of the CCI pilots in terms of care delivery models being tested and size of pilot populations, contractors may be hesitant to risk using case

management fees for expanding IT adoption or paying physician case managers for performance in the early stages of the program.

In developing health care improvement targets for CCI contractors and their physician case managers, it is important for CMS to keep in mind that these performance goals be limited to elements of care completely under the physician's control. To the degree possible, each physician case manager's caseload must be appropriately risk adjusted for the complexity of their patients, while patients who fail to comply with prescribed care plans should not be counted when measuring physician performance.

The CCI program is available to a wide array of organizations: Health insurers, disease management companies, physician group practices, integrated delivery systems, consortia of these entities, and any other legal entity that meets the requirements of the solicitation in the Federal Register. The scope of the CCI program is vast, operating in at least 10 pilot locations and requiring each contractor to oversee the care of 15,000 to 30,000 Medicare beneficiaries—far out of the reach and capabilities of the small physician group practice. Among ACP's practicing members, 67.4 percent are in practices of 10 or less, while 50.2 percent are in practices of 5 or less. Clearly, the CCI program is biased in favor of large organizations such as DMs, making it virtually impossible that a small physician group practice could win a CCI contract.

Since, by statute, elements of the CCI program pilots which prove themselves successful will eventually become a permanent components of Medicare, it is critically important to have practicing physicians fully vested in the all the care models tested, in order to demonstrate that physician case management is the key to successful CCI efforts

4. ***Use of Advanced Information Technology Should be an Essential Element of CCI Phase I Pilot Testing***

ACP is a strong advocate of bringing the advances of information technology (IT) to enhance the quality of patient care, as reflected in two major papers released in 2004 (see references at end of this testimony). We believe optimal case management of chronic care patients cannot occur without instantly accessible electronic information from all sources of care, the goal of an interoperable national health care information system—a goal ACP supports and is actively pursuing. The CCI program represents an ideal opportunity to provide incentives for adoption of quality enhancing IT. Having rapid electronic access to all vital patient information, as well as clinical decision support software such as ACP's Physician Information and Education Resource, will be crucial in assuring the physician case manager can optimally serve his/her patients, which is why incentives for IT adoption are so important. The CCI program's Request for Proposal (RFP) does encourage contractors to assist care providers in adopting enhanced communications technology, though any such support they provide to physicians and other providers must come out of their negotiated case management fee.

However, ACP believes there is sufficient leeway for CMS, in negotiating case management fees and health improvement targets with contractors, to allow contractors to offer information technology incentives. ACP would thus urge CMS to assign one or more of its pilot sites to test use of these additional incentives.

Summary

ACP strongly encourages CMS to ensure that one or more of its CCI pilot sites utilize a patient-centered, physician-guided approach to care as defined above, to be certain this model is fairly evaluated against all other models tested. ACP also urges this model include a physician case management fee and incentives for physician performance and IT adoption. If such a model is not selected for testing in Phase I of the CCI program, ACP would ask Congress to pass corrective legislation to address this major oversight.

ACP also heartily endorses CMS's stated goals for the CCI pilot program, listed on the CMS website, as follow:

- It leads toward a stronger focus on improving health outcomes for prospectively identified targeted populations who are not well served by the fragmented FFS health care delivery system.
- It creates a new focus on setting measurable performance goals and tracking improvements in clinical quality, provider and beneficiary satisfaction, and cost-effectiveness in a regional, population-based framework.
- It develops and tests the concept of tying contractor payment to results in achieving quality and cost targets and satisfaction levels.

- It helps modernize Medicare by creating incentives for the private sector to harness advances in information technology and innovation in care management on behalf of FFS Medicare beneficiaries
- It addresses quality failings without changing beneficiary's benefits, providers, or access to care.
- It is an approach that is regional, yet potentially replicable nationally.
- It is a substantial investment for those beneficiaries who need it most that will help reduce avoidable costs.
- Minority populations suffer disproportionately from chronic diseases and will stand to benefit most from the program.

ACP urges CMS to ensure that a physician-centric CCI model is tested at a least one of its 10 pilot sights. ACP also stands ready to work with any CCI bidders that offer a physician-centric model that includes the incentives identified above, and would also encourage use of its clinical decision support tool, PIER. For any bidder which offers a physician-centric model which, upon close inspection meets all ACP requirements, the College may be willing to endorse the bidder's proposal and encourage ACP members residing in that particular geographic area to participate in the pilot program

References

[1] The Paperless Medical Office: Digital Technology's Potential for the Internist, ACP Discussion Paper, March 2004. Available at: http://www.acponline.org/hpp/paperless.pdf?hp

[2] Enhancing the Quality of Patient Care Through Interoperable Exchange of Electronic Healthcare Information, ACP Policy Paper, April 2004. Available at: http://www.acponline.org/hpp/quality_care.pdf?hp

Statement of American Geriatrics Society, New York, New York

The following written testimony is on behalf of the American Geriatrics Society (AGS), an organization representing geriatricians and other health care professionals dedicated to the care of older adults.

Brief History of Geriatrics

Geriatric medicine promotes preventive care, with emphasis on care management and coordination that helps patients maintain functional independence in performing daily activities and improves their overall quality of life. With an interdisciplinary approach to medicine, geriatricians commonly work with a coordinated team of other providers such as nurses, pharmacists, social workers, and others. The geriatric team cares for the most complex and frail of the elderly population.

Geriatricians are primary—care oriented physicians who are initially trained in family practice or internal medicine, and who, since 1994, are required to complete at least one additional year of fellowship training in geriatrics. Following their training, a geriatrician must pass an exam to be certified and then pass a recertifying exam every 10 years. There are almost 7,000 geriatricians in the United States.

The Frail Elderly/Chronically Ill Population

Americans are not dying typically from acute diseases as they did in previous generations. The Partnership for Solutions, a Robert Wood Johnson founded initiative of which we are a partner, has found that about 78% of the Medicare population has at least one chronic condition while almost 63% have two or more. Of this group with two or more conditions, almost one-third (20% of the total Medicare population) has five or more chronic conditions, or co-morbidities.

In general, the prevalence of chronic conditions increases with age—74% of the 65 to 69 year old group have a least one chronic condition, while 86% of the 85 years and older group have at least one chronic condition. Similarly, just 14% of the 65–69 year olds have five or more chronic conditions, but 28% of the 85 years and older group have five or more.

Medicare Reform and the Geriatric Patient: How Does Disease Management Differ from Geriatric Care?

The Medicare program has recently undergone major reforms: the addition of outpatient prescription drug coverage and disease management. Will these new changes address the problems faced by frail older persons and the physicians who treat them?

Little is being done to change the nature of the system from acute episode care to sustained chronic care. As today's hearing notes, the Medicare bill included several new chronic care provisions, including a new study on chronic care, a small scale physician-oriented demonstration program, and, of relevance today, a larger scale disease management pilot program. Unfortunately, the new disease management program may not adequately address the needs of persons with multiple chronic conditions.

The new disease management pilot program establishes chronic care improvement organizations (CCIOs) under the Medicare fee-for-service program. CCIOs, which may include disease management organizations, health insurers and integrated delivery systems, will be required to improve clinical quality and beneficiary satisfaction and achieve spending targets in Medicare for beneficiaries with certain chronic conditions. CCIOs will be held at full risk for their role in helping beneficiaries manage their health through decision-support tools and the development of a clinical database to track beneficiary health.

Why aren't disease management programs sufficient to transform the system of care for frail older persons?

Disease management covers many different activities influencing individual health status and the use of health care services. Typically, disease management programs treat patients with specific, clearly-defined diseases, such as diabetes, asthma, congestive heart failure or chronic obstructive pulmonary disease where the evidence is clear and management strategies are straightforward. Disease management focuses on patient education and evidence-based self-management strategies as tools to improve care. Disease management relies on improved disease outcomes to improve health and reduce disease-specific health care utilization. Patients who are the best candidates for disease management programs are those who have the motivation and cognitive skills to appreciate their role in illness management and implement self-management strategies.

Geriatric care is another term for coordinated care or care management. Care coordination programs generally enroll patients with multiple chronic conditions. The combinations of conditions puts the patients at high risk of medical and social complications that requires specific interventions tailored to the specific needs of each enrollee. These interventions include an array of services, such as telephone coordination with other physicians, extensive family caregiver support, referrals for social supports, and high levels of medication management.

While disease management is appropriate for certain Medicare beneficiaries with a single chronic condition, such as diabetes, asthma or hypertension, it fails to address key issues for patients that have multiple chronic illnesses and/or dementia. This issue is further explored below.

First, disease management is not typically appropriate for persons with more than one chronic condition. Imagine putting a patient with diabetes, hypertension, dementia, asthma, and COPD into a disease management program for each of these conditions. Most of the people who are most costly to Medicare have multiple conditions and the care for these people can not be segmented into different disease management programs. In fact, many of these individuals with one or more chronic conditions also have Alzheimer's disease or another dementia. Disease management focusing on diabetes without taking dementia into account wouldn't be successful. While some disease management companies suggest that they have taken a new holistic approach to patient care, this evidence remains anecdotal.

Second, when used for patients with multiple co-morbidities, disease management can disrupt a patient's critical relationship with a primary care physician. Some disease management programs utilize specialists that focus only on specific interventions tailored to one condition. The nature of chronic illness requires a comprehensive, care coordination based approach that utilizes a variety of interventions. Disease management programs that lack a physician component do little to coordinate the care of older persons with multiple illnesses and little to mitigate the safety hazards of fragmented, redundant care delivered by multiple providers. Significantly, a recent, large-scale Mathematica best practices study noted that maintaining and fostering the physician-patient relationship is critical to the success of chronic care delivery.

Third, a major component of disease management involves self-management and patient education. These simply do not work for persons with Alzheimer's disease or a related dementia. Diabetes self management often involves patient education or patient self management which is inappropriate for a beneficiary with Alzheimer's disease or related dementia. Likewise, disease management for asthma and hypertension depends on patient compliance with treatment recommendations; this would not be effective for persons with Alzheimer's disease or related dementia. In

comparison, care coordination models rely on engaging family and caregivers and maximizing their involvement.

Fourth, disease management does not always address functional issues that are common in old age or the complications that arise from multiple chronic illnesses.

Fifth, treatment guidelines provide little guidance when multiple chronic illnesses co-exist. Therapeutic decisions are less straightforward, making treatment decisions less amenable to algorithmic self-management protocols.

Finally, disease management programs place little importance on using social support services, a major component of a care coordination approach which relies on a holistic model of patient care.

Additional physician participation and attention to the needs of multiple chronic conditions and especially dementia could improve project outcomes, but the model remains different from the approach of a new fee-for-service care coordination benefit.

Instead, the AGS recommends the legislative authorization of a new Medicare fee-for-service chronic care benefit, which would include a physician assessment and team based care management benefit. This is based on the Geriatric Care Act, legislation introduced in the House by Congressman Gene Green (D–TX) and in the Senate by Senator Blanche Lincoln (D–AR) and the Medicare Chronic Care Improvement Act, legislation introduced in the House by Congressman Pete Stark (D–CA) and in the Senate by Senator John D. Rockefeller IV (D–WVA).

Conclusion

While the introduction of the CCIO program represents a modest step forward in the delivery of chronic care, we remain convinced that a significant portion of our nation's needs will remain unmet without the addition of a related but different physician directed chronic care benefit within the fee-for-service system. We hope to work with the Subcommittee on Health on such a change.

Statement of Sandeep Wadhwa, McKesson Corporation, San Francisco, California

I am pleased to submit this statement on behalf of McKesson Corporation to the Subcommittee on Health of the House Committee on Ways and Means, subsequent to the May 11, 2004 hearing on the Medicare Chronic Care Improvement Program (CCIP).

As the world's largest healthcare services company, McKesson is an industry leader in the provision of disease management services to the Centers for Medicare and Medicaid Services (CMS) through our Medicaid fee-for-service contracts with seven states. We commend the members of the Committee and the Congress for incorporating a disease management program for Medicare beneficiaries within the Medicare Modernization Act and are pleased to share our perspective on the use of disease management programs to improve quality and clinical outcomes in CMS populations while decreasing health care costs.

Our disease management clients cover a broad host of purchasers of health care, including:

- *State contracts for the Fee-for-Service Medicaid* populations in Mississippi, Washington, Oregon, Colorado, Florida, New Hampshire, and Montana
- *Managed Medicaid plans* such as Triple-C (Puerto Rico) and the Santa Clara Family Health Plan
- *Individual high risk insurance pools* like CoverColorado and the Oklahoma Health Insurance High Risk Pool, Utah High Risk Pool
- *Commercial health plans* such as Blue Cross Blue Shield Federal Employees Program and Blue Cross Blue Shield of Texas
- *Medicare+Choice plans* such as Order of Saint Francis and Group Health Insurance

McKesson is the industry leader in care management services and software and also has market leadership positions in demand management and utilization criteria. Furthermore, we are leading providers of physician and quality profiling software and case management workflow software. As an early provider of these programs, we have been delivering disease management services since 1996. McKesson's disease management programs leverage our experience with patient services, pharmacy management, and health care quality improvement activities. Many of these programs and services reflect the capabilities and expertise of our

170 year old company, one of the largest nationwide distributors of pharmaceuticals and health care products and the largest health information technology company in the world.

Over the past three years, many states have turned to disease management programs to help contain their rising Medicaid budgets and provide better services for low-income population groups. Our analyses of the Medicaid fee-for-service (FFS) population show a surprising similarity to many of the issues confronting the Medicare FFS population. In particular, the blind and disabled Medicaid utilization patterns are similar to the Medicare population that we serve in Medicare+Choice plans. Like the Medicaid FFS blind and disabled population, the Medicare population has highly complex health care needs. Both groups are considered vulnerable populations because of their age, poverty or disability. Additionally, both are able to see any physicians or emergency rooms that accept Medicaid or Medicare payment.

In the following sections, we provide comments on the CCIP through the lens of our experience overseeing similar interventions in the Medicaid FFS population. Some of the specific concerns likely to be factors in the CCIP have been addressed in our Medicaid FFS experience.

Patient Identification and Participation

One of the most significant barriers to the success of the CCIP will be successfully engaging patients to participate in these interventions in a manner that is respectful and non-discriminatory. Experience in the Medicaid fee-for-service setting is illustrative. Patients are identified for these programs primarily through historical claims analysis. This process is highly efficient and accurate and allows for a comprehensive population based identification method rather than relying on costly and more fallible chart reviews at physicians' offices. Initially, the physicians of these identified patients are also contacted. Direct mailings then go out to the patients informing them of the chronic care management program's design and goals. Community based awareness campaigns help to raise awareness among patients and physicians.

Once patients have been identified, enrollment campaigns ensue. Initial enrollment and assessment takes place telephonically or through face-to-face meetings with patients. In our experience, fewer than five percent of eligible patients have opted out of these programs, and the highest rates of participation are among those who are the sickest, the frailest and the most vulnerable. These patients are also the heaviest utilizers of services and thus afford the greatest opportunities for generating savings. Interviews we have conducted indicate tremendous appreciation for these outreach services. These programs also comply with all HIPAA standards. The proposed methodology for enrollment for the CCIP by CMS will largely follow this Medicaid model. In our experience, this process is highly respectful, professional, and well-received by beneficiaries.

In the Medicare population, we also anticipate much higher rates of cognitively impaired beneficiaries due to dementia, which is similar to the cognitive impairment of the Medicaid population due to schizophrenia. Disease management programs which serve the Medicaid schizophrenia population make strong efforts to involve the beneficiaries' caregivers. Caregiver involvement is a key tenet for all disease management programs; for patients with cognitive impairments and insight disorders, it is especially critical. Our experience has shown that caregivers appreciate the emotional support, skill training, and counseling services that are provided. Furthermore, we have found that these programs help sustain and renew caregivers in providing care for an often unappreciated and demanding role. Similar services need to be provided to those who are acting as caregivers to the Medicare population.

Provider Involvement

During the recent hearing, concern was expressed that those who are awarded CCIP contracts to provide disease management services will find it challenging "to develop the necessary links with physicians".[1] Most disease management programs are successfully able to overcome physicians' concerns that these programs replace or disrupt their care. Prior to contacting patients, disease management organizations typically engage in an extensive physician awareness campaign about the programs' methods and objectives. These efforts have dramatically eased physicians' concerns about the nature of disease management programs and have increased physician participation. It is critical to educate physicians that disease management programs promote adherence to their treatment recommendations and provide their

[1] Robert Berenson, Testimony to Subcommittee on Health of House Ways and Means Committee, May 11, 2004.

patients with education services to augment their efforts. In Mississippi, McKesson has partnered with the University of Mississippi Medical Center and with the Mississippi Primary Health Care Association, the Mississippi trade organization of community health centers, to educate Mississippi providers about the disease management initiative. Similar types of interventions will be beneficial for providers before Medicare patients are enrolled.

A key issue in treating the Medicare population is the slow adoption of national clinical practice guidelines. The elderly are more apt to be under treated. An important component of disease management interventions is to accelerate the adoption of these national clinical practice guidelines. Patients are educated on the guideline recommendations and encouraged to discuss the appropriateness of the recommendations with their physicians. Disease management firms are able to present reports to physicians on the gaps that exist between practice and guideline recommendations. Patient safety deliberations often focus on medical errors that have been committed, rather than on errors which result from omitted treatment. Through clinical decision support tools and patient empowerment, disease management programs are designed to reduce these errors of omission.

Care Coordination

In Medicare FFS, patients often see multiple physicians without one serving as a primary coordinator of care. The absence of a physician "quarterback" contributes to excessive testing, medication errors, and miscommunications. A key dimension of the CCIP will be to assist the patient in identifying a "medical home", which is a physician or a clinic primarily responsible for treating and managing the patient's chronic condition. Once a medical home is established, the disease management nurse cements the relationship by serving as an advocate for the patient and informing the physician of symptoms, self management practices, and gaps with nationally accepted clinical guidelines. The quality of the patient/physician interaction is enhanced through patient education and nurse advocacy.

CMS has recommended greater communication and collaboration among those involved in caring for the elderly, and the CCIP provides incentives for such increased collaboration between disease management organizations and providers. McKesson welcomes the opportunity to further integrate our services and enhance our collaboration with provider organizations to fulfill the vision of a population-based, patient-centered, provider-coordinated chronic care model.

Proven Benefits from Disease Management Programs

McKesson programs have demonstrated dramatic improvements in the health status of patients, with marked reductions in hospitalization and emergency room visits that have resulted in net reductions in health care costs. In order to achieve improved outcomes, our programs focus on teaching patients self-management principles, symptom control strategies and optimal medical management practices. Overall, patients in our programs have reported very high satisfaction with the service and noted improvements in their overall quality of life. Attached are case studies that summarize the positive results achieved in the Washington, Oregon and Mississippi state Medicaid programs.

Conclusion

In conclusion, the experience we have obtained from providing Medicaid FFS disease management services indicates that many of the expected barriers and concerns with the Medicare population can be addressed and overcome. Realization of cost savings, patient participation, provider involvement, adherence to guidelines and coordination of care are all barriers that have been surmounted in similar settings, through a rigorous process that provides the necessary respect and privacy for those who participate in the program. The outcomes-focused, evidence-based interventions provided in disease management programs improve patients' ability to participate in their care and to assist physicians by reinforcing their medical recommendations. As Congress continues to deliberate about new ways to improve the quality and delivery of health care, we believe the greater utilization of disease management programs is a vital way to enhance care outcomes for the elderly and other vulnerable populations while concurrently reducing the cost of delivering better care.

We look forward to working with you and members of this Subcommittee as you address these important concerns.

Statement of Brian J.G. Pereira, National Kidney Foundation, New York, New York

The National Kidney Foundation (NKF) congratulates Congress for authorizing the Secretary of the Department of Health and Human Services to develop a program of chronic care improvement under Subtitle C of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). This program could promote better outcomes for the 20 million Americans who have chronic kidney disease and are at risk for developing End Stage Renal Disease (ESRD), many of whom are Medicare beneficiaries. Nevertheless, we maintain that this chronic care improvement program would be enhanced if the Centers for Medicare and Medicaid Services (CMS) included a specific focus on chronic kidney disease in its implementation of the legislative mandate. We recommend that this be accomplished in two ways: first, by establishing a chronic care improvement program specifically designed for Medicare beneficiaries with chronic kidney disease, and secondly, by refining the request for applications for diabetes care and heart failure that the CMS published on April 20, 2004. Evidence-based clinical practice guidelines developed by the NKF provide the scientific foundation for the development of the programs that we recommend. Those guidelines are part of NKF's Kidney Disease Outcomes Quality Initiative (K/DOQI) program.

I. **Basis for a Chronic Care Improvement Program for Chronic Kidney Disease**

MMA provides that chronic care improvement programs shall be designed to improve clinical quality and patient satisfaction for Medicare beneficiaries with one or more threshold conditions as well as enhance provider satisfaction and reduce avoidable costs. The term "threshold condition" is defined in section 721 (a)(2)(D) of Public Law 108–173 as a chronic condition, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), **or other diseases or conditions, as selected by the Secretary as appropriate for the establishment of a chronic care improvement program."** (Emphasis added.) For the reasons stated below, we believe that chronic kidney disease meets the statutory criteria for a chronic care improvement program.

a. The K/DOQI Guidelines for the Evaluation, Classification and Stratification of Chronic Kidney Disease establish that chronic kidney disease is a major public health problem in the United States, based on data from the 1998 report from the third cycle of the National Health and Nutrition Examination Survey (NHANES III). NHANES III, conducted from 1988 to 1994, estimated that 6.2 million individuals over 12 years of age had reduced kidney function, as defined by serum creatinine concentration. This represents an almost 30-fold higher prevalence of reduced kidney function compared to the prevalence of ESRD during the same interval.
b. Timely identification and treatment of patients at risk of developing End Stage Renal Disease is crucial. The United States Renal Data System's (USRDS) 2003 Annual Report estimates that the number of patients with ESRD may reach 2.24 million by 2030. (As of December 31, 2002 there were a total of 297,928 people on dialysis in the U.S.) The rates of ESRD are high in both minority and elderly populations and the projected growth of minority populations, coupled with the rising age of the post-World War II "baby boomers," show the potential for a dramatic increase in the number of people needing ESRD therapy in the next 30 years. Disease management could play a significant role in delaying and preventing the progression of chronic kidney disease and/or its complications and, thereby reduce avoidable costs. See, for example, the study by Hock Yeoh, et al., "Impact of Predialysis Care on Clinical Outcomes," published in *Hemodialysis International* last year.
c. The K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification specify the diagnostic criteria that can be used to identity patients in the various stages of chronic kidney disease and suggest interventions that would be appropriate to prevent or delay the progression of chronic kidney disease and/or its complications at each stage.

II. **Kidney Disease and Chronic Care Improvement for Diabetes and Heart Failure**

The Notice that CMS published on April 20, 2004 to implement the Section 721 initiative reads: "In these initial programs, we will focus primarily on implementing and evaluating programs for beneficiaries with congestive heart failure (CHF) and/or **diabetes with significant co-morbidities (hereafter referred to as com-**

plex diabetes).” (Emphasis added.) However, the terms “diabetes with significant co-morbidities” and “complex diabetes” are not defined anywhere in this 76-page document. The CMS should specify that kidney disease is a significant co-morbidity for Medicare beneficiaries with diabetes and that relevant diagnostic and therapeutic interventions for individuals with diabetes and kidney disease be included in proposals to participate in this pilot project.

According to the USRDS 2003 Annual Report, the population of existing patients whose ESRD is caused by diabetes, which tripled from 1990 to 2000, is expected to grown ten-fold by 2030, to 1.3 million, and the number of patients diagnosed each year with ESRD caused by diabetes is expected to grow from 41,000 in 2000 to 300,000 in 2030, a 600 percent increase. Furthermore, according to Guideline 14 of the National Kidney Foundation’s Guidelines for Evaluation, Classification and Stratification of Chronic Kidney Disease, the risk of cardiovascular disease, retinopathy and other diabetic complications is higher in patients with diabetes and kidney disease than in diabetic patients without kidney disease.

An expanded focus on chronic kidney disease in Medicare beneficiaries with diabetes would require expansion of the initial chronic care improvement program guidelines. For example, on April 20, 2002, the CMS published a core set of clinical quality indicators for which applicants are required to establish expectations. “Monitoring for nephropathy (test for microalbumin)” is appropriately included among the diabetes measures. On the other hand, there is an important indicator of chronic kidney disease missing from this core set. Medicare beneficiaries with diabetes should be evaluated for possible decline in kidney function through estimates of Glomerular Filtration Rate (GFR). GFR estimates are the best overall indices of the level of kidney function. Individuals with reduced GFR should, in turn, be evaluated and treated for complications of reduced GFR. This includes measurement of anemia, nutritional status and bone disease. Estimated GFR should be monitored yearly in patients with chronic kidney disease and diabetes.

Similarly, non-diabetic patients with chronic kidney disease have an increased prevalence of cardiovascular disease compared to the general population. (K/DOQI Guideline 15 for Evaluation, Classification and Stratification of Chronic Kidney Disease.) Measures for chronic care improvement for Medicare beneficiaries with heart failure should be expanded to include assessment of kidney function (by GFR measurement) and kidney damage (by tests for protein in the urine).

III. **Conclusion**

The National Kidney Foundation respectfully requests that the Committee monitor the implementation of the MMA chronic care improvement program by the CMS to insure that Medicare beneficiaries with chronic kidney disease, as a co-morbidity with diabetes and/or heart failure, benefit to the fullest extent possible from the agency’s initial program announcement. Furthermore, while diabetes is the largest single cause of End Stage Renal Disease, constituting 44% of new ESRD cases annually, more than half of new ESRD patients do not have diabetes. Additionally, there could be millions of Medicare beneficiaries with chronic kidney disease but without diabetes, who could benefit from the diagnostic and therapeutic interventions that are recommended by the K/DOQI program. Therefore, we respectfully request that the Committee urge the CMS to develop a chronic care improvement program for chronic kidney disease in the near future.